PreFIT
PREVENTION OF FALL INJURY TRIAL

MULTIFACTORIAL FALL PREVENTION MANUAL

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Glossary and definitions

Angina	Chest pain caused by ischaemia to the heart muscle tissue (myocardium).
Arrhythmia	An irregular heart beat, including bradycardia or tachycardia.
Benzodiazepines	A class of drugs to treat anxiety, epilepsy, mania, sleeping difficulties and alcohol withdrawal. Side effects can cause drowsiness, unsteadiness and memory problems.
Bradycardia	Slow heart rate, usually defined as <60 beats per minute although symptoms often do not occur unless heart rate <50 bpm. Context should be considered as fit, athletic adults have a slower heart rate.
Carotid sinus syncope	Fainting (syncope) caused by over-stimulation or over-activity of the carotid sinus, a receptor located in the carotid arteries of the neck. This can occur from wearing a tight collar, turning the head or looking up.
Carotid sinus massage	A process whereby the carotid sinus receptors, located in the arteries of the neck, can be stimulated manually to assess for hypersensitivity. Manual stimulation may cause changes in heart rate, blood pressure and can lead to temporary loss of consciousness (syncope).
Cluster RCT	A cluster trial is where a group of participants are randomisation to receive the same intervention together e.g. the cluster can be the general practice or a hospital rather than an individual person. PreFIT randomises a general practice to deliver either an intervention or control because this is easier to deliver and prevents 'contamination'.
Contamination	The inadvertent treatment with the intervention when someone is in the control group, or vice versa. Thus any unintended impact of the intervention on an individual in the control group, as might happen if a GP alters their 'usual care' applied to a control group participant (if they have recently treated another patient in the active intervention group). Hence the use of the cluster trial design which reduces the risk of this, as the practitioner is exposed only to control or intervention, not a mixture of both.
Dizziness or giddiness	Defined as feeling dizzy or giddy, light-headed, feeling as if going to faint. See vertigo.

Falls history	Asking a participant about their history of falling. Involves taking a clinical history, exploring using a qualitative approach, about the factors that led to the fall. This includes context of fall, such as place and activity at the time.
Integrated falls service	Falls service working within a defined casemix of patients and working to agreed protocols and pathways.
Medication review (DH definition)	Structured review of the efficacy and continuing appropriateness of a patient's medication.
Medication review (ProFaNE definition)	Comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events with a special focus on medications associated with an increased fall risk e.g. antipsychotics, sedatives, hypnotics, antidepressants, antiarrhythmics, anti-convulsants, anxiolytics, antihypertensives and diuretics.
Multi-agency service	A service that involves different agencies e.g. health, social services and/or voluntary sector.
Multi-factorial falls risk assessment	An assessment of different risk factors for falling. For the purposes of PreFit, this includes assessment of: falls history, red flags, gait and balance, medication review, postural hypotension, vision, feet/ footwear and environmental factors.
Multi-professional service	e.g. medical, nursing, physiotherapy, occupational therapy, social work.
Otago Exercise Programme	A progressive, individualised strength and balance retraining programme developed and tested in New Zealand. It has been shown to prevent falls in older adults.
OTC	Over the counter non-prescription medications purchased from pharmacies and other outlets.
Palpitations	An abnormality of heartbeat that results in an awareness of the heart thumping in the chest (can be regular, irregular, fast or slow).
Peripheral fracture	This is the primary outcome for the study, defined as 'any non-spinal, non-pelvic fracture.' This definition is based on work conducted by the ProFaNE research group.
Polypharmacy	Four or more medications being on a patient's medication list – either prescribed or over the counter drugs. This may not necessarily be harmful and may indeed by necessary. However, polypharmacy is a risk factor for potential harm from medication.

Postural hypotension	A sustained reduction of systolic blood pressure of at least 20mmHg systolic (or below 100mmHg) or diastolic blood pressure of 10mmHg within 3 minutes of standing after having been lying down.
Pragmatic study	A study (usually a trial) that is designed to reflect how the intervention works within the real life situation e.g. within the usual healthcare setting.
ProFaNE	Prevention of Falls Network Europe – European Commission funded collaboration to reduce the burden of fall injury in older people through excellence in research and promotion of best practice.
Proprioception	The (unconscious) perception of movement and spatial orientation. Awareness or sense of position, location and orientation of the body.
Psychotropic medication	Any drugs used to treat psychoses and related disorders; also includes antidepressant drugs.
Random allocation	A method that uses the play of chance to assign participants to different groups in a trial. For PreFIT, general practices will be randomly allocated to deliver advice, exercise or MFFP. The randomisation procedure is done using a computer-generated random sequence (with a stratification variable added).
Randomised Controlled Trial (RCT)	An experiment where 2 or more interventions are tested against a control or comparison group, using random allocation.
Red flags	Term used to denote a sign or symptom that requires appropriate action e.g. such as referral to another health care specialist. Example may include bradycardia with syncope.
Snellen Chart	A contrast chart used to test visual acuity.
Syncope	Syncope refers to a temporary or transient loss of consciousness (fainting) with spontaneous recovery. This can be caused by loss of blood flow to the brain.
Tachycardia	A fast heartbeat, usually defined as >100bpm.
Vertigo	A sensation of spinning.
Visual acuity	Acuteness or sharpness of vision.

CHAPTER 1

Introduction to Manual

1. INTRODUCTION TO MFFP MANUAL

1.1 Introduction

This is the multifactorial falls prevention (MFFP) manual for the Prevention of Fall Injury Trial (PreFIT). This manual has been written and designed for health professionals involved in the delivery of falls prevention services to older persons participating in the PreFIT study. Some healthcare professionals will have considerable experience of working in falls services prevention and will be very familiar with the rationale for falls prevention, assessment procedures, definitions and recommended treatment pathways. However, not all those working from this manual will have the same level of background training and experience therefore the manual has been developed to account for differing levels of skill, training and clinical expertise.

The **aims** of this MFFP manual are:

- To provide the scientific research evidence about the components within MFFP programmes and to describe the model selected for use in the Pre-FIT study;
- To explain the rationale for the chosen study design;
- To describe procedures for the assessment and treatment of trial participants who have been referred to MFFP services;
- To describe trial documentation and adverse event reporting procedures.

There are different sections to the manual:

- **Chapter 2** provides an overview of scientific evidence for falls prevention programmes.
- **Chapter 3** describes the rationale, aim and design of the PreFIT study.
- **Chapter 4** provides an overview of the PreFIT MFFP intervention, including the risk factors, recommended treatment pathways and how this relates to current UK national guidance.
- **Chapters 5 to 11** provide background information for each risk factor separately. A full description of “how to” assess each risk factor is given with recommended treatment pathways for when a risk factor is identified. At the end of the risk factor chapters, examples of 3 case studies are provided.
- **Chapter 13** describes trial reporting procedures and related documentation,

including processes for reporting adverse events within the trial.

1.2 Usual care vs PreFIT care

This study manual will be given to primary and secondary care teams responsible for the assessment and treatment of older adults participating in PreFIT. We recognise that the content and procedures contained within this risk assessment manual may differ from the care usually delivered by your service e.g. there may be differences in the risk factors contained within the manual or in the recommended treatment pathways. This is to be expected and we acknowledge there is considerable variation in both type and delivery of falls services across the UK. However, for the purposes of a clinical trial, it is crucial that all healthcare providers use the **same processes** to assess risk of falling and adhere to the same treatment pathway if a risk factor has been identified. Therefore this manual has been produced to 'standardise' the study MFFP intervention, to reduce the risk of differences arising between different care centres and providers. Therefore, for **all PreFIT trial participants** referred to your service, we ask that you adhere to the content of this manual when assessing risk of falls. This should not affect your usual care of other non-trial patients referred to your service. You may decide to use some of the approaches within the manual for non-trial participants if you so wish.

1.3 The PreFIT Study Research Team

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Professor Lamb is Director of the Warwick Clinical Trials Unit and is the Chief Investigator who has overall responsibility for the PreFIT study. Dr Julie Bruce is the research lead, also responsible for co-ordination and delivery of trial interventions. Julie is the first point of contact for any queries about the multifactorial falls prevention intervention, manual and related materials. As Trial Co-ordinator, Emma Withers is the administrative manager and has responsibility for day to day management and delivery of the trial. Ms Susanne Finnegan is a research physiotherapist with overall responsibility for the exercise intervention. Mr Rhys Mant (not pictured) is the Trial Administrator.

Other key PreFIT study team members include:

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Copyright Statement

CHAPTER 2

Background to Falls Prevention Programmes

2. EVIDENCE FOR FALLS PREVENTION PROGRAMMES

2.1 Early strategies to prevent falls

Falls are a common problem among older adults with approximately 30% of those aged over 65 years, living in the community, falling each year. Although less than 1 in 10 adults who fall sustain a fracture, many fall incidents require medical attention (Gillespie et al, 2003). Falls can result in pain from injuries, long-term disability and also mortality. Early reports of identifying risk factors for falling emerged from the USA in the late-1980s. This work, which focused on strategies to identify and reduce multiple risk factors, now termed multi-factorial fall prevention (MFFP), was conducted in Connecticut and funded by the National Institute on Aging (Tinetti et al, 1994). The central theme of this research agenda was that falls and immobility do not result from increasing age alone, but from the accumulated effect of multiple impairments and disabilities (Tinetti et al, 1994; Koch, 1994). As such, many of these impairments are modifiable, suggesting that falls and immobility can be reduced. The '**Tinetti multifactorial fall programme',** tested within early explanatory trials, although small, were promising – results suggested that treatment of common health problems and hazards in older people decreased falling by more than 30% (Tinetti et al, 1994; Close et al, 1999).

2.2 Fall prevention programmes: the UK setting

Evidence from the early multifactorial falls prevention programmes provided the foundation for the National Service Framework for Older People to mandate the NHS to establish MFFP programmes for people with a history of a fall (i.e. secondary prevention), and subsequently, for NICE to endorse this recommendation (NICE, 2004). Consequently, many specialist falls prevention services were established throughout the UK, although this process was disparate, with variation in service development and models of delivery across different settings. An appraisal of fallers' clinics was launched by NICE in 2004 but was subsequently suspended because of lack of information regarding existing services and their typology.

2.3 UK Audit of falls services

In 2007, a National Scoping Audit was launched to evaluate Faller's Clinics in the UK (Lamb et al, 2007). This national audit revealed that most MFFP services in the UK consisted of multidisciplinary teams (92%) although these ranged widely by both size

and discipline represented. Of the 231 MFFP services responding to the national audit exercise, multifactorial assessment was conducted by almost all services (99%) and this consisted of: gait and balance assessment (91%), environment assessment (76%), medication review (72%), cardiovascular (69%) and, to a lesser extent, vision assessment (58%). Assessments of feet, bone health and hearing were conducted less frequently (<50% of services) although some clinics did involve podiatrists and, for example, specialist dietetic staff. Of those surveyed, 83% of MFFP clinics matched interventions to the findings of assessments: common interventions included information provision (94%), exercise interventions (89%) and medication reviews (66%) (Lamb et al, 2007).

2.4 Systematic reviews of fall prevention programmes

There are now over 100 published trials investigating the efficacy of fall prevention initiatives, but many of these studies have small sample sizes and are of low methodological quality. In 2003, a Cochrane systematic review included only **four** good quality trials investigating the effectiveness of multidisciplinary, multifactorial, health/environmental risk factor screening and intervention programmes: these trials suggested a **27%** reduction in falls for unselected older populations in the community (Gillespie et al, 2003). For older adults with a history of falling or who were selected because of known risk factors, a 14% reduction in risk of falling was observed across five trials. There was insufficient evidence to know whether MFFP programmes prevented fall-related injuries. One of the drivers for preventing falls is to prevent factures and injuries - falls cause fractures which lead to hospital admission and are associated with disability and loss of independence. Fractures are costly to treat and require substantial amounts of care.

2.5 Recent trials of MFFP interventions

Since publication of the original MFFP studies and the Cochrane systematic review, there have been several other well-conducted, large trials in the UK and Netherlands investigating the effectiveness of MFFP. These studies, somewhat surprisingly, found **no evidence** of fall or fracture reduction (Lord et al, 2005). Additionally, recently updated high quality systematic reviews concluded that MFFP might be substantially less effective than previously thought and possibly not effective at all (Gates et al, 2008; Gillespie et al, 2003); (Gillespie et al, 2009), updated Cochrane review). This means that there is a possibility that tax-payers money is being

directed towards strategies that are not effective and this money could be reinvested towards more effective strategies for falls and fracture prevention in older people in the community.

2.6 Is exercise effective in preventing falls in older adults?

There have been other trials investigating the benefits of exercise in preventing falls among older adults living in the community. Exercise, specifically training in strength, balance and flexibility, has been shown to be effective in reducing falling in older adults. People, even aged in their 90s, can improve their strength and balance to achieve stability and avoid falls. Our best estimate is that exercise reduces falls by about 25%, although this is dependent upon the casemix and upon the mode and intensity of exercise (Gillespie et al, 2009). There are some difficulties with exercise, in particular, with ensuring that people take enough exercise, and that they adhere to it in the longer term.

2.7 Is exercise more effective than MFFP?

At present, we do not know how **exercise** and **MFFP** programmes compare because there have been no studies directly comparing one against the other. There have been no studies directly comparing MFFP programmes to exercise only to investigate whether there is any added benefit from a more comprehensive programme. It is also crucial to consider the impact of programmes in preventing falls-related injury (fractures) in older adults. It may be that the exercise component within MFFP programmes contributes most to the reduction in falls and fractures. If so, this is important because exercise may be a safer, cheaper and more acceptable option for delivering services to older patients. Furthermore, adherence to exercise to achieve the necessary ‘dose’ might be adversely affected by simultaneous participation in other interventions.

CHAPTER 2. Key Points

- Early studies of MFFP programmes reported a 30% reduction in falls in older adults.

- More recent studies found that MFFP programmes are substantially less effective than previously thought.

- Exercise, particularly strength and balance training, is effective in reducing falls in older adults.

- No large, well-conducted study has directly compared exercise with MFFP in preventing falls and fractures in older people living in the community.

CHAPTER 3

The PreFIT Study

Aims, Objectives & Trial Design

3. AIMS OF PREFIT STUDY

3.1 Rationale for PreFIT

Given the background of clinical uncertainty described in Chapter 1, there is a need to conduct a large, well-designed study to compare different strategies for preventing falls and fractures among older adults living in the community. The **P**revention of **F**all **I**njury **T**rial (PreFIT) has been designed for this purpose. It is a multi-centre, 3-arm, **cluster-randomised, controlled trial,** with economic analysis. The trial will evaluate the clinical and cost-effectiveness of three primary care fall prevention interventions: (1) advice alone, (2) advice supplemented with exercise and (3) advice supplemented with MFFP. These trial interventions – exercise and MFFP - are currently widely available in the UK, but little is known about their comparative effectiveness. The PreFIT trial therefore will provide evidence about which is the most effective and cost-effective service for reducing falls and fractures in community-dwelling older adults.

3.2 Aim of PreFIT

The **primary objective** of the trial is to establish the comparative effectiveness of three primary care fall prevention interventions (advice, and advice supplemented with either exercise or MFFP) for older people living in the community. The study aims to contribute evidence to inform UK healthcare practitioners, commissioners and other stakeholders on the relative effectiveness and cost-effectiveness of a range of primary care options for preventing falls and fractures. The PreFIT study is using **peripheral fracture rates** as the primary outcome, therefore a very large trial is required to detect a difference in peripheral fractures between groups. For the purposes of this study, peripheral are defined as any non-spinal or non-pelvic fracture. The PreFIT study will recruit 9000 older adults across different regions in England.

The **secondary objectives** are to:

- Measure the uptake of the active interventions (i.e. exercise and MFFP) and quantify observed differences;
- Assess the relative effectiveness of interventions for the prevention of falls and peripheral fractures in people of different ages, gender and fall history;

- Assess the relative costs of each intervention and establish the most cost-effective approach for preventing falls and fractures.

These results should also enable us to estimate the population impact of the intervention in terms of peripheral fractures, taking into account the differential effectiveness and different fracture incidence in subgroups of the older population.

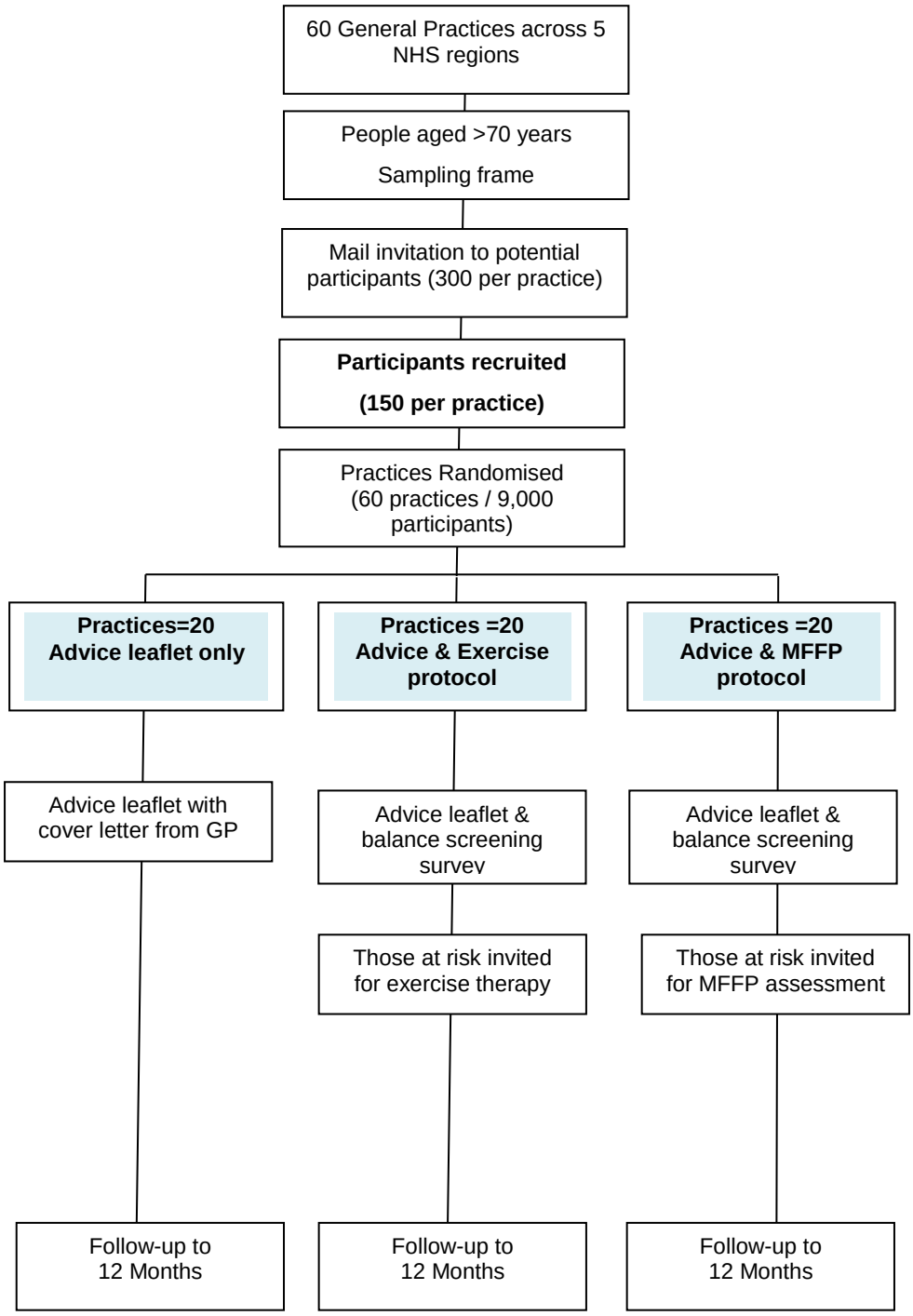
3.3 Study design

The PreFIT study is a pragmatic cluster randomised controlled trial (RCT), with the unit of **randomisation** being the general practice or 'cluster' rather than individual study participants (see Glossary). This cluster design has been selected to avoid **contamination** – it would be difficult for GPs to randomize individual patients to different treatment interventions in the same practice and to study uptake of different interventions. Hence a cluster design was chosen. A **pragmatic study** means that the trial has been designed to reflect the real life situation within the healthcare setting. Thus rather than examine Pre-FIT interventions under ideal or tightly controlled experimental conditions, the study will examine how these interventions are delivered within the pressures and constraints of the existing healthcare setting and environment. Figure 1 displays a flowchart of recruitment processes for the trial.

3.4 Does the trial have ethical approval?

In the UK, all research involving data collected from NHS patients must be approved by a research ethics committee. The PreFIT study has full ethical approval from a multi-centre research ethics committee (MREC) with additional site specific approval from each participating region. Approval has also been obtained from R&D departments within NHS Healthcare/ Primary Care Trusts from participating regions.

Figure 1 - Trial Flow Diagram



3.5 Who is eligible to participate in the PreFIT study?

The trial will recruit 9000 adults over the age of 70 years, who live in the community, either at home or in sheltered accommodation. Of those recruited and consented to participate, GPs will then screen for risk of falls using a simple postal questionnaire. PreFIT study participants will be referred for falls assessment based on responses to this self-screening survey. You will assess participants who are considered at intermediate or high risk of falling (Box 1) You are being asked to assess and treat older adults, who live in the community, who have identified themselves as being at risk of falling and are willing to undergo assessment and treatment. This patient group, therefore, may differ slightly from the 'usual' patient referred for falls risk. An additional objective of the study is to assess the uptake of services by those deemed at risk.

Box 1 - PreFIT participants referred for MFFP assessment

PreFIT Study Entry Criteria

- Aged over 70 years;
- Live in the community at home or in sheltered accommodation;
- Person has life expectancy of >6 months;
- GP considers eligible for inclusion in the trial;
- Has consented to participate in study.

Referral criteria:-

- Person has fallen twice or more in the last year; *or*
- Person has fallen once in the last year and has balance difficulty; *or*
- Person has not fallen in the last year but they report balance difficulties or other difficulty with particular daily activities, such as dressing, bathing etc.;
- Person not currently attending a falls service.

3.6 Does the PreFIT study adhere to current national guidance on falls prevention?

The National Institute for Clinical Excellence (NICE, 2004) has published recommendations for screening for risk of falls; this states that all older adults, defined as those aged over 65 years, should be screened and advised about risk of

falls when they come into contact with *any* healthcare provider. However, recent audits have shown that this is not always the case. One recent National Audit of Falls and Bone Health in older people (RCP, 2010) found that even when older people attend hospital with serious fall-related injuries (e.g. fracture), they are not being properly assessed in order to prevent further injuries. One key conclusion from this national audit was that "most primary care organisations lack adequate services for secondary falls and fracture prevention". The PreFIT study does focus on primary rather than secondary prevention, thus aims to prevent falls and fractures rather than treat those who have already fallen. One third of PreFIT trial participants will receive an advice leaflet, as this is included in NICE guidance as a standard intervention (refer to AgeUK leaflet, Appendix 1). This advice leaflet may be more than is currently provided to older adults, given the pressures and demands on existing primary care services (Box 2).

Box 2 - Advice on falls prevention

Despite national guidance recommending that older adults should be screened and advised about risk of falls when they come into contact with any healthcare provider, national audits show this is rarely the case (NICE, 2001; NICE, 2004). This is perhaps understanding, particularly when falls prevention is not currently part of the NHS Quality and Outcomes Framework (QOF) and given current multiple pressures on GP consultation time.

An advantage of the PreFIT trial is that all participants will receive high quality general advice about falls prevention in the form of a comprehensive AgeUK leaflet. This advice leaflet is designed to encourage those who are fit and well to remain this way, and for those who are not, it provides "self-help" tips.

CHAPTER 3. Key Points

- The PreFIT study is an NHS Health Technology Assessment-funded research study which uses a multicentre, pragmatic, cluster, randomised controlled trial (RCT) design.

- The trial is based in primary care and will a sample of community-dwelling older adults aged over 70 years

- The three interventions are advice only, advice plus exercise or advice plus MFFP on outcomes of peripheral fractures (primary outcome) and falls

- The PreFIT study uses a primary-care screening approach (balance screener) to identify participants at risk of falling.

- A subgroup of recruited participants will be offered MFFP assessment

CHAPTER 4

The PreFIT MFFP Intervention

An Overview

4.1 The Tinetti Model of Falls Prevention

The national UK survey of falls clinics identified various models of falls prevention services. For the purposes of the PreFIT study, the original multifactorial falls prevention programme from Connecticut (Tinetti et al, 1994) was selected as the MFFP model of choice. As stated in Chapter 2, this programme found that treatment of common health problems and hazards decreased falling by more than 30%. The **Connecticut Collaboration for Fall Prevention,** based at Yale University School of Medicine, encouraged local clinicians in the Connecticut area to incorporate fall risk assessment and treatment into their care of older adults. The common problems and hazards associated with falling included: difficulties with walking or moving around; multiple medications; tripping hazards; postural hypotension; visual problems; foot problems and unsafe footwear. The original USA 1994 protocol and exercise (physical) therapy component was developed using a consensus approach with experienced geriatricians, physical therapists, home-care and rehabilitation nurses. The core components of the original Tinetti model included assessment and treatment of different risk factors (Box 3). This model was implemented in a subsequent trial, whereby practitioners adhered to assessment and treatment components (Tinetti et al, 1994).

Box 3 - Risk factors included within the USA Model (Tinetti et al., 1994; 1995a; 1995b)

- Impairment of gait, transfers or balance;
- Multiple (≥4) medications or ”culprit” medications;
- Postural hypotension/dizziness;
- Perception/sensory deficits: vision, hearing, feet (decreased position sense)
- Foot (pain, numbness, bunion etc.) or footwear problems;
- Environmental hazards.

4.2 Adaptations to the Tinetti Model for the PreFIT study

The protocol and materials developed by the Connecticut research team are widely available to other clinicians and healthcare workers (Tinetti et al, 1988; Tinetti et al, 1994). For the purposes of PreFIT, the original Tinetti programme has been modified for use in the UK healthcare setting. Adaptations have been made to update the original programme to comply with UK national recommendations and latest evidence e.g. NICE Clinical Practice Guideline (NICE, 2004); British Geriatrics Society (BGS)/American Geriatrics Society (AGS) 2010. The NICE 2004 guideline was developed from a series of in-depth, high quality systematic reviews of falls prevention and treatment literature. The PreFIT MFFP intervention therefore complies with latest research evidence and national evidence-based guidance.

4.3 The need for standardisation

As described in Chapter 3, there are different models of MFFP falls prevention services in the UK, e.g. community health falls services, secondary care-led services, and other models with appropriately trained healthcare professionals (e.g. primary care). We believe that the most feasible and generalisable model for PreFIT, given the large numbers involved, is primary care based services or local community multidisciplinary falls services. However, referral to a secondary care specialist service is also another possible and acceptable model of delivery.

4.4 Components included within the PreFIT MFFP intervention

The core components of the PreFIT MFFP intervention include assessment and treatment of seven risk factors (Box 4). The assessment of 'red flags' (see page 38) is integral within taking a falls history although it has been listed as a separate risk factor on the summary pictorial assessment sheet (Appendix 10). Risk assessment is linked to recommended treatment pathways however treatment or intervention **is only required** where a particular risk factor has been identified.

4.5 Advice about foot care and footwear.

Although NICE reviewed studies of feet/footwear/podiatry interventions, no specific guidance or advice relating to footwear or foot care was provided within clinical

practice statement. The AGS/BGS guidance graded evidence for inclusion of feet/footwear components within MFFP interventions as "C" [*no recommendation for or against the routine provision of the intervention is made. At least fair evidence was found that the intervention can improve health outcomes, but the balance of benefit and harm is too close to justify a general recommendation].* However, the AGS/BGS do recommend that examination of the feet and footwear and appropriate treatment (unspecified) should be included within MFFP interventions. The PreFIT programme therefore has included assessment and treatment for foot problems (Chapter 9).

Box 4 - Components within the PreFIT MFFP intervention

Risk factors included within PreFIT intervention (NICE/AGS-BGS guidance)	Excluded risk factors
✓ Falls history & red flags	X Hearing
✓ Impairments of gait and balance	X Osteoporosis
✓ Postural hypotension	X Cognitive impairment
✓ Multiple or 'culprit' medications	X Neurological examination
✓ Vision	X Carotid sinus hypersensitivity
✓ Foot problems	
✓ Environmental hazards	

Box 5 - Summary of risk factors, assessment and treatment options

Risk factor	Assessment conducted by trained assessor[1]	Recommended treatment pathway (if risk factor identified)
History of falling	Conduct detailed falls history. Check for red flags.	Refer to appropriate service for further investigation if warranted.
Gait and Balance	Timed Up and Go Test. History of tripping /stumbling/loss of balance. Using furniture whilst walking.	Refer to physiotherapy services for strength and balance retraining (Otago Home Exercise Programme).
Postural Hypotension	Pulse, lying/standing BP.	Medication review. Refer to other services if cardiac disease suspected.
Type of medication	Review number, class of prescribed medications also use of OTC's.[2] Check whether on psychotropics.	Reduce or eliminate culprit medications, night sedation and anti-psychotics.
Vision	Eye test history & Snellen test.	Refer to optician for eye check. Refer to ophthalmology services if eye disease suspected.
Foot problems	Visual inspection of feet and footwear.	Provide advice. If indicated, arrange referral to local NHS podiatry/chiropody services or recommend appointment at private services. Refer to Otago Home Exercise Programme if foot placement/balance compromised.
Environmental hazards	Screen for potential home hazards.	Give advice leaflets. Arrange referral to occupational therapy for home assessment if indicated.

[1] Falls risk assessment can be conducted by nursing or other healthcare staff who have completed PreFIT training.

[2] Medication reviews may be conducted by non-medically trained staff but all changes **must** be checked, approved and signed by a medically trained practitioner.

4.6 Components not included in the PreFIT programme

a) Hearing

The original Tinetti MFFP model included checks for impaired hearing as a risk factor for falling. However, recent NICE and AGS/BGS guidance do not include recommendations for the assessment and treatment of hearing problems within MFFP programmes. Although trials have included assessment of hearing within multifactorial interventions, these trials have either been methodologically flawed or failed to demonstrate any reduction in falls (NICE, 2004). The PreFIT MFFP intervention, therefore, does not include assessment of hearing problems.

b) Risk of osteoporosis

Osteoporosis is loss of bone mass and destruction of bone tissue which causes weakening of the bones making them more likely to fracture. Postmenopausal women are most at risk of developing osteoporosis; other risk factors include increasing age, diet, lifestyle factors, chronic inflammatory diseases, diabetes and certain medications. There are different tools to estimate risk of fragility fracture both in individuals who have had a fracture and those who have not (e.g. FRAX risk assessment http://www.shef.ac.uk/FRAX). Certain drugs, such as the bisphosphonates e.g. alendronate, are recommended as treatment for preventing fractures in postmenopausal women who have had osteoporosis diagnosed but have not had a fracture (NICE, 2011). Guidelines on the prevention and treatment of osteoporosis and on the use of Vitamin D for fracture prevention are currently in development (and revision) by NICE. For the purpose of the PreFIT study, we have not included an assessment of risk of osteoporosis.

c) Cognitive impairment and neurological examination

Patients with severe cognitive impairment will be ineligible for inclusion, however it is possible that patients with mild cognitive impairment participate in the study. It is also very possible that for some participants, cognitive ability will decline during the course of study follow-up. The PreFIT MFFP intervention does not include detailed assessment of cognitive impairment or detailed neurological examination. The NICE guidance review found no evidence that cognitive/behavioural interventions alone reduce the incidence of falls in community-dwelling older people (NICE, 2004). There was also no evidence that complex behavioural interventions, such as group

activities (education, behaviour modification programmes) were effective in falls prevention in community-dwelling older people. The PreFIT study will assess cognitive function within baseline and follow-up data instruments.

d) Carotid sinus hypersensitivity

Cardiac pacing (insertion of a pacemaker) is effective in reducing falls and syncope in community-dwelling older adults with cardioinhibitory carotid sinus hypersensitivity who have experienced unexplained falls. NICE guidance does state that cardiovascular assessment should be carried out within a multifactorial assessment, where appropriate (NICE, 2004). This guidance is based on evidence from one trial which found a statistically significant reduction in falls and syncope after cardiac pacing for cardioinhibitory carotid sinus hypersensitivity in fallers who attended a hospital emergency department (Kenny, 1999). The AGS/BGS guidance also states that dual chamber cardiac pacing should be considered for older persons with cardioinhibitory carotid sinus hypersensitivity who experience unexplained falls. For the purpose of PreFIT, we ask assessors to check heart rate and screen for postural hypotension. For safety reasons, bearing in mind the different clinical backgrounds of practitioners conducting assessments (and possible barriers to accessing clinicians in community settings), we **do not recommend** that carotid artery stimulation be conducted to check for carotid sinus hypersensitivity. If a participant has experienced unexplained falls, these should be referred to a consultant-led falls or secondary care service for further assessment. Unexplained recurrent falls might represent the effect of syncope or transient pre-syncopal disturbance to cerebral blood flow sufficient to induce a fall in an individual with other risk factors. In this instance, referral for consultant led assessment is recommended.

4.7 The next chapter

The next section of the manual describes each of the individual risk factors included within the PreFIT intervention: falls history with red flags, gait and balance, postural hypotension, vision, medication reviews, foot assessment and environmental modifications. Each chapter provides background details and relevant definitions for each of the included risk factors. A description of “how to” assess each risk factor and a recommended treatment pathway is provided.

CHAPTER 4. Key Points

- The PreFIT MFFP intervention is based on the Tinetti (1994) programme with modifications to comply with current UK national guidance on falls prevention.

- The key components of the PreFIT MFFP intervention include: conducting a falls history/checking for red flags; assessment of gait and balance, postural hypotension, medication screen and review, vision, foot problems and consideration of the home environment.

- The PreFIT MFFP intervention focuses on individualized assessment and targeted referral for further treatment or intervention if a risk factor is identified.

- Most, but not all, of the PreFIT MFFP intervention can be conducted by a suitably trained, non-medical healthcare professional – however, this **must** be supplemented with onward referral and/or discussion with a suitably trained medical practitioner e.g. GP or consultant-led falls service if indicated.

- A non-medically trained healthcare practitioner can complete falls assessment materials for PreFIT study participants. However, a medically trained practitioner **must approve** any changes to medication resulting from a medication review.

CHAPTER 5

Risk assessment

Falls history interview & red flags

Risk assessment: History of falling

5.1 Conducting a falls history assessment

The purpose of eliciting a falls history in an older person is to identify and explore any predisposing factors leading to a fall. It is important to explore the context and consequences of any previous falls – this could provide clues about causation. Eliciting a falls history involves good communication skills and systematic enquiry about fall-related events. When conducting the interview, provide clear explanations, free from jargon which the patient can understand. The interviewer should develop the skills to follow relevant leads in the conversation and use a good balance of open, exploratory and closed questions. The interview should be conducted at an appropriate pace without rushing the person and without inappropriate interruptions during their explanations of events.

5.2 When taking the falls history

It is important to get a clear story of one specific event, usually the most recent fall. Take the patient through the event from before, during and afterwards. The context may be quite mundane but still important to establish. A fall occurs in an individual with a specific mosaic of characteristics, (some of which might increase their falls risk), in a specific context such that their postural stability is overcome. The risk of falling has been shown to increase as the number of these risk factors increases. Any context can be described in terms of the “falls hazards” they contain. The magnitude of association of a fall with any intrinsic or environmental factor is not fixed, but is mutually interdependent and contingent on additional factors influencing performance of the specific activity in question.

So the question is not only why the patient was prone to falling, but also why did the fall happen on that particular occasion? This approach leads to identifying intrinsic risk factors, relevant activities and environmental challenges, any of which may be amenable to modification.

Another factor to explore during the interview is fear or worry about falling. Fear of falling is common in elderly people and is associated with poor balance, anxiety,

depression, and falls. These fears may be reasonable and suggest good awareness about actual falls risk, or fears may be exaggerated, suggesting the person might be overly anxious.

5.2 Definition of a fall

The recommended definition of a fall is “an unexpected event in which the participant comes to rest on the ground, floor or lower level.” (Lamb et al, 2005a). However, for the purposes of interviewing, the following lay definition of a fall should be used – “in the last year (or state timeframe), have you had any fall including a slip or trip in which you lost your balance and landed on the floor or ground or lower level?” These definitions were generated and agreed by the Prevention of Falls Network Europe (ProFaNE), a collaborative project funded by the European Commission (Lamb et al, 2005b). Although the PreFIT study recommends asking about any falls in the last year, recall bias can be a problem. Research evidence suggests that older adults can recall falls in a general way over a 1-year period, but recall for the precise timing of events in the previous 3 to 6 months can be more problematic (Lamb et al, 2005a).

5.3 Red Flags

Red flags are warning signs that referral to a GP or medical specialist may be warranted. For example, a participant with cardiac abnormalities, such as bradycardia and a history of near fainting or syncope will require referral to a local specialist service for falls/syncope assessment. Other examples that **will require referral** to specialist assessment include symptoms suggestive of seizure activity such as visual aura and tongue biting.

Taking a good falls history is an important skill which can be honed over time. There is no single question or validated algorithm to follow when elucidating an accurate falls history – it requires good listing skills and also the ability to link different risk factors to each other e.g. visual problems may relate to tripping with the home or outdoors; dizziness on standing may be related to particular psychotropic medications etc. Refer to the example case studies provided at the end of this section of the manual.

RISK FACTOR ASSESSMENT a) Taking a Falls History

Conducting the falls history interview

Introduce yourself and explain the purpose of the appointment. Screen for falls by using the falls history screening questions in Box 6 below. For non-fallers with balance difficulties, explore circumstances and context further by asking about types of balance difficulties. For example, enquire about dizziness, weakness in the legs, any palpitations or visual disturbances (see Table 1 below). For those participants who have fallen before, conduct a full falls history and explore the factors using the questions listed in the Box 6 below.

Box 6 - Falls history screening questions to ask during interview

Q1. Have you fallen in the last 12 months?

If yes or no, continue to Q2.

Q2. Do you have any difficulties with your balance whilst walking or dressing?

If the person has not fallen but has balance difficulties, select appropriate questions to explore further.

Table 1 - Questions to use during a falls history interview

Question	Possible / probable cause of falls & onward treatment pathway
Any dizziness or giddiness?	Dizziness or giddiness defined as feeling dizzy or light-headed, as if going to faint. Ask about circumstances. Check for postural hypotension (Chapter 7).
Any vertigo?	A sensation of spinning. May represent vestibular disease which requires medical diagnosis.
Any muscle weakness in the legs? Is one leg weaker than the other?	If the person has one leg weaker than the other, this requires a full medical review. Refer to consultant-led falls service or secondary care.
Any sudden loss of consciousness?	Any sudden, unexplained loss of consciousness (syncope) requires a medical review. Reasons may include anything from a vasovagal faint to a cardiac arrhythmia or other cardiac problem. Requires referral

	to consultant-led falls service (secondary care).
Any palpitations or angina?	See definitions. Suggestive of cardiac disease. Ask about exercise-related chest pain. The first stage for referral is to the GP unless the pain is present at time of assessment (if so, urgent referral to secondary care for cardiac assessment.).
A trip or stumble on a hazard? Explore circumstances.	Ask about home environment (Chapter 11).
Any rapid position change?	May indicate postural hypotension or if head movement, may indicate carotid sinus hypersensitivity. Continue with falls assessment and consider referral to consultant-led falls service/ secondary care. This may also indicate visual dependency for stability due to vestibular insufficiency (with or without vertigo).
Any visual disturbance, such as blurred vision?	May indicate epileptic fit or may indicate visual problems associated with tripping on hazard. Continue with assessment also conduct vision check (Chapter 9).
Any injuries sustained from the fall, bruising, fractures etc.?	May indicate sudden drop and unable to protect themselves. Continue with falls assessment and consider other circumstances.
Any facial injuries?	Similarly, indicative of sudden fall and unable to protect themselves. Continue with falls assessment and consider referral to consultant-led falls service/ secondary care.
Any tongue biting?	Suggestive of epileptic fit. Ask about incontinence. Refer in the first instance to the GP who may refer to consultant-led falls service/ secondary care.
Were they wearing a very tight collar around the time of the fall?	Indicative of carotid sinus hypersensitivity. This will require referral to a consultant-led falls service.
Have they ever been incontinent when/after falling?	May indicate epileptic-type seizure. Enquire about tongue biting. Consider referral to consultant-led falls service.
Do you worry about your balance?	May indicate fear of falling. May benefit from balance retraining and reassurance.

CHAPTER 6

Risk Assessment:

Disturbances of gait and balance

Risk assessment: Disturbances of gait and balance

6.1 Background

Most exercise interventions to prevent falls in older adults focus on strength and balance training to improve gait and transfers. **Gait** refers to the manner in which someone walks and relates to walking patterns. **Balance impairments** include impairments of sitting, standing or dynamic balance. This relates to postural balance or the biomechanics of the musculoskeletal system during standing, walking, sitting and other movements. In an examination of gait pattern, you are looking for evidence of shuffling or feet not picking up, slower gait, shorter steps, or broad-based gait, postural instability and altered balance responses. Postural instability can be caused by altered proprioception and slowed processing, which can lead to increased sway whilst walking.

6.2 Gait and balance assessment tools

There are many published gait assessment tools: e.g. the survey of falls services revealed 28 different screening tests were used throughout the UK (Lamb et al, 2007). These included the Tinetti Performance Orientated Mobility Assessment (POMA) balance test, the Stops Walking When Talking, Timed Up and Go Test and Berg Balance test. The Tinetti programme developed the POMA Balance Test, a task-orientated test that measures gait and balance ability (Tinetti, 1986). This screening test takes 10-15 minutes to complete and incorporates aspects of sitting balance, standing balance, turning, gait initiation, step length and height, step symmetry/continuity, path, trunk sway and walking stance. A total of 16 items of balance and gait are assessed and scored.

The NICE (NICE, 2004) Clinical Practice Statement states that for falls screening purposes, a simple observation of ability to stand, turn and sit is considered adequate as **first level assessment**. Therefore for the purposes of PreFIT, we ask that assessors use the Timed Up and Go Test. This has advantages in that it is simple and easy to administer in the primary care setting.

6.3 Treatment of gait and balance problems

Gait retraining is the specific correction of walking technique (e.g. posture, stride length and cadence) and changes of pace, level and direction (Lamb et al, 2005b). Balance training is defined as the efficient transfer of bodyweight from one part of the body to another or challenges specific aspects of the balance systems e.g. vestibular systems. Balance retraining activities range from the re-education of basic functional movement patterns to a wide variety of dynamic activities that target more sophisticated aspects of balance. All gait and balance functional training should be based on an *assessment* of the participant's abilities prior to starting the programme; *tailoring* of the intervention to the individuals abilities; and *progression* of the exercise programme as ability improves.

6.4 Recommended PreFIT treatment: The Otago Exercise Programme

There are various different exercise interventions to prevent falls in older adults. The PreFIT trial recommends the **Otago Exercise Programme** (OEP) for strength and balance retraining exercises. The OEP focuses on strengthening leg muscles, using ankle cuff weights for resistance, with a series of progressive balance exercises and a walking plan. Physiotherapists will be trained in the Otago programme and will be asked to deliver the intervention to trial participants referred for exercise therapy.

6.5 Using the Timed Up and Go Test

The Timed Up and Go Test was developed as a basic test for functional mobility (Podsiadlo & Richardson, 1991). The test includes standing up from a standard chair (with arms) of seat height between 40-50cm, walking a distance of three metres at a normal pace, turning, and then walking back to the chair to sit down. The procedure is timed in seconds; the original study, conducted with elderly patients with neurologic conditions, found that those taking longer than 30 seconds to complete the test were at higher risk of falls. However subsequent research with community-dwelling, frail older adults used a TUGT test using a **14 second** cut-point which was predictive of falls (Shumway-Cook et al, 2000). This study also used a chair with arms and people were told they could push off using the arms of the chair when standing, if they needed to.

Given that PreFIT is using a primary prevention approach to prevent falls in community-dwelling older adults, we recommend that 14 seconds be used as the TUGT cut-point. This is a simple test which does not require equipment or extensive training therefore is convenient and quick for use in clinical settings. The subject should wear their regular footwear and walk using their usual walking aid.

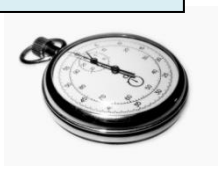
For the purpose of PreFIT, we ask that during the TUGT assessment, you also observe for other gait-related problems e.g. stride length, foot clearance, veering to one side, grabbing or lunging for furniture in the room. Another factor to consider is whether the person is fearful of moving or turning. Fear or worry about balance is a risk factor for falling and should be explored during the assessment (see next few pages). Appendix 11 is a laminated guide to the TUGT.

RISK FACTOR ASSESSMENT b) Gait and Balance

Screening for gait and balance

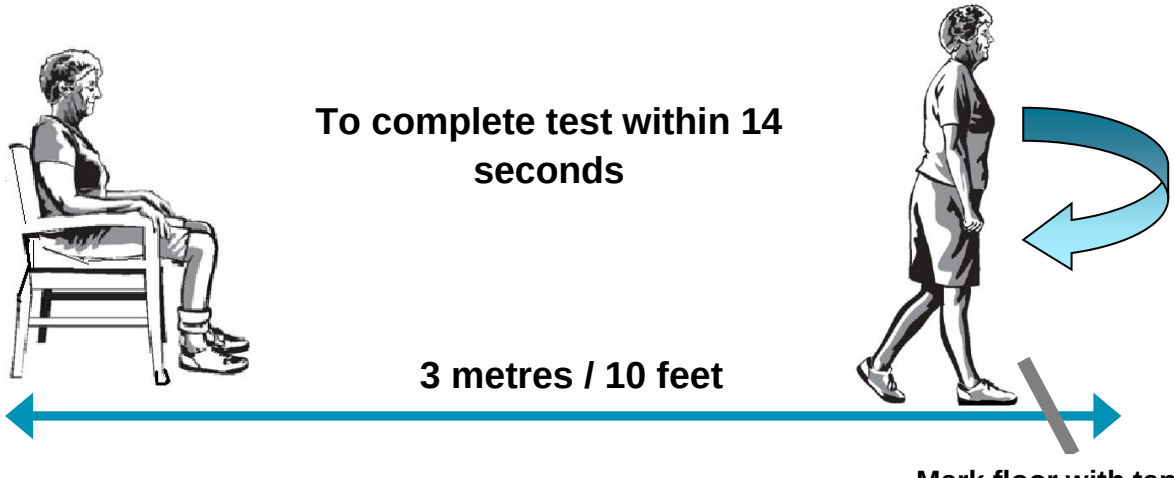
- Use the Timed Up and Go Test to screen for gait and balance problems
- Gait analysis: observe for unsteadiness, shuffling walk, uneven stride length

Items required: stopwatch & measuring tape (provided)



Procedure for TUGT

- Ensure that the chair is hard-backed with arms, of seat height between 40-50cm.
- Position the chair so that you can clearly observe the person walking.
- Ensure that there is enough room to walk a length of 3 metres (10 feet) from the chair. Use the length of tape to measure the correct distance.
- We will provide tape to indicate the correct distance.
- Explain the procedure and demonstrate if necessary.
- Person wears regular footwear and uses their usual walking aid. They can use the arms of the chair to push off if necessary.
- Use the stop watch provided to time the procedure.
- Instructions to patient: “When I say go, I want you to stand up, walk to the line, turn and then walk back to the chair and sit down again. Walk at your normal pace”
- Also observe gait pattern, look for postural sway and attempts to grab at furniture.
- Start stopwatch on the word **‘GO’** and stop timing when they **sit down** again.



Scoring of test

- Record the time taken (in seconds) on the Falls Risk Assessment Form (Appendix 3).
- If participant takes longer than 14 seconds to complete, then refer to physiotherapy services for gait and balance retraining.
- Consider gait pattern and if unsteady, or if attempt to use furniture for support, refer to physiotherapy services for gait and balance retraining.
- Observe for postural sway during the test. Also observe ability to get up and sit down from a chair, ability to stand with feet together, and any problems with turning around. Refer to physiotherapy services for gait and balance retraining.
- Also consider responses to falls history screening questions when deciding to refer for gait, balance and strength training.
- Is the participant worried about their balance? Are they fearful of falling? Do they need balance retraining to improve confidence and steadiness?
- Record if the participant is unable to perform the test – record 'test aborted' on the Falls Risk Assessment Form.
-

Treatment Options & Actions Required

Refer if TUGT takes longer than 14 seconds to complete **OR** if participants has balance/gait problems that would benefit from physiotherapy training e.g. reports repeated tripping or stumbling during falls history interview.

Initiate referral pathway to local physiotherapy services for Otago Exercise Programme.

CHAPTER 7

Risk Assessment:

Postural Hypotension

Risk assessment: Postural Hypotension

7.1 Assessment of postural hypotension

Postural hypotension, or orthostatic hypotension, is defined as: “a sustained reduction of systolic blood pressure of at least 20mmHg OR a drop in systolic blood pressure to below 100mmHg OR a reduction of diastolic blood pressure of 10mmHg within 3 minutes of standing” (Freeman et al, 2011). There are numerous different cut-off values for postural hypotension, however, a standard definition was agreed by the 1996 multi-speciality Consensus Conference sponsored by the American Academy of Neurology and the American Autonomic Society. This consensus statement was updated in 2011 (Freeman et al, 2011). The definitions and descriptions in the updated consensus statement have been used for the PreFIT study. The prevalence of postural hypotension increases with age, due to weakening of the postural compensatory mechanisms. Postural hypotension can occur in patients with neurogenerative disorders, Parkinson’s disease, pure autonomic failure and with disorders that affect the autonomic nerves (Freeman et al, 2011). However, postural hypotension can also occur as a benign, transient event, e.g. light-headedness due to dehydration, fever, infection, over-exertion or from exercise.

Box 7 - Definition of postural hypotension

Blood pressure measurement — Systolic
Diastolic

A sustained reduction of systolic BP of at least 20mmHg **or** a drop in systolic BP to below 100mmHg **or** a reduction of diastolic BP of 10mmHg within **3 minutes** of standing.

Patient has postural hypotension if they are symptomatic and have any of the following:

- any drop in systolic BP of at least 20mmHg **OR**
- any drop in diastolic BP of at least 10mmHg on standing up. BP should be taken immediately on standing with a cut-off time of **3 minutes OR**
- if the systolic BP drops to below 100mmHg.

7.2 Features of postural hypotension

Symptoms of postural hypotension include light-headedness, dizziness, pre-syncope or a feeling as if going to faint, and syncope (fainting). Some patients do present with more general complaints including: fatigue, weakness, cognitive slowing, leg buckling, visual disturbances e.g. blurring, headache, neck pain, breathlessness or chest pain (Freeman et al, 2011). Loss of consciousness is usually of gradual onset but may occur suddenly.

7.3 Syncope

Syncope refers to a transient loss of consciousness (fainting) with spontaneous recovery within minutes that can be caused by loss of blood flow to the brain – termed 'global cerebral hypoperfusion'. Syncope is usually a transient brief occurrence that resolves as soon as pulse/BP returns to normal. For instance, if BP drops on standing, as soon the person lies down, they then recover.

Syncope may not necessarily mean serious medical disease, however it is important to determine the cause. Other causes of loss of consciousness may be traumatic (e.g. head injury) or non-traumatic e.g. epilepsy, metabolic or cardiac disease (Freeman et al, 2011). Epilepsy is usually a more prolonged loss of consciousness followed by a 'post-ictal' phase with a longer recovery period. Cardiac causes may relate to cardiac arrhythmias (slow, fast or irregular heartbeat). Cardiac pacing, or a pacemaker, may be required to treat bradycardia.

7.4 Treatment of Postural hypotension

Diuretics, anti-hypertensives and other vasodilators may contribute to a drop in blood pressure on standing. These drugs may include blood pressure lowering medications, antidepressants, in particular tricyclic agents, alpha-blockers used for prostate problems and selected anti-Parkinsonian drugs. Therefore if a participant is found to have postural hypotension, the first line of treatment is to conduct a full medication review (see Chapter 8). If postural hypotension continues after medication review and modification, then referral to a local consultant-led falls service may be indicated. If there signs of bradycardia with syncope, this also requires referral to a consultant-led falls service.

RISK FACTOR ASSESSMENT c) Postural Hypotension

Screening questions for postural hypotension

Q1. Do you ever feel dizzy or lightheaded if you stand up too quickly?

Q2. Do you ever feel dizzy or lightheaded first thing in the morning when you get out of bed?

Regardless of response to Q1 or Q2, check heart rate and rhythm. Take lying and standing blood pressure.

Procedure

- We ask that you use a manual or electronic syphgomanometer. Ensure that machines have been recently checked and calibrated.
- Explain the procedure. Ask participant to lie on couch.
- Wait for 2 to 3 minutes before taking first reading. Record radial pulse and assess rate/rhythm (sinus bradycardia (<50 bpm), sinus tachycardia (>100 bpm), other).
- Take lying BP and record.
- Ask to stand, repeat measurement on same arm, as soon as standing and within 3 minutes of standing. Record measurement.

Scoring

- Record radial pulse and whether regular or irregular.
- Test is positive if drop in systolic BP of at least 20mmHG within 3 mins standing.
- Test is positive if drop in systolic BP <100mmHg within 3mins standing.
- Test is positive if drop in diastolic BP of at least 10mmHG within 3mins standing.

Treatment options / Actions Required

- Conduct full medication review and consider drugs that may cause hypotension.
- An electrocardiogram (ECG) should be recorded for anyone with an irregular pulse, bradycardia or tachycardia.
- Use an electronic ECG machine with a report.
- If this is not available, the ECG should be interpreted by a doctor, specialist nurse or trained cardiac technician.
- Use the findings from the ECG to inform your decision about treatment or referral for further assessment e.g. cardiology or medical referral.
- If postural hypotension, change timing of diuretics to avoid nocturnal micturition.
- If postural hypotension, give information leaflet (see Appendix 8) which provides advice about changing position slowly, not to walk when dizzy, how to tighten calves when getting up from a lying position etc.
- Consider referral to consultant-led falls service if arrhythmia with syncope.

CHAPTER 8

Risk Assessment:

Medication Use

Risk assessment: Medication use

8.1 Polypharmacy in older adults

Older patients consume increasing numbers of prescription medications, over-the-counter (OTC) medications, and other supplements. Four in five adults aged over 75 years take at least one prescribed medicine, with 36% taking four or more medications (DH, 2002). Whilst medications improve disease outcomes and provide symptom relief, multiple medications compromise adherence and increase the likelihood of adverse medication effects. There is good evidence to suggest that patients take, on average, only half of their prescribed medications as intended (RPSGB, 1997). The more medications prescribed, the lower the adherence. This finding highlights the need for prescribers to carefully consider each medication as it may compromise adherence to other medications.

The ageing process affects capacity to absorb and excrete medicines. In addition, the **risk of adverse effect increases 10%** with each additional medication, approaching 100% for persons receiving 10 or more medications (Tinetti et al, 1994). Many adverse reactions to medicines could be prevented – adverse drug reactions are implicated in 5-17% of hospital admissions (DH, 2002). It is important to balance disease and symptom prevention and management against the adverse effects of multiple medications. In the absence of an easy method for determining “net benefit vs. harm of a patient’s total medication regimen”, there are some general principles and specific steps that can lessen the likelihood of adverse effects of multiple medications.

8.2 Culprit medications

Benzodiazepines and anti-psychotic medicines are often inappropriately prescribed for the elderly; these can contribute significantly to risk of falls (DH, 2002). The original Tinetti programme highlighted specific classes of high-risk medications, using the term ‘**culprit’** medication for any class considered to be high risk. These included: anti-hypertensives, anti-arrhythmics, anti-convulsants, anti-depressants, anti-histamines, anti-psychotics, benzodiazepines, decongestants, diuretics, opiods and urinary anti-cholinergics. Some commonly prescribed medicines, including anti-depressants, digoxin and lithium can cause problems – also non-steroidal anti-

inflammatory drugs (NSAIDs) can cause interactions with other drugs. In 2010, the National Falls and Bone Health Audit in Older People specifically highlighted **psychotropic medication** and **night sedation** as potential causes of falling.

8.3 Evidence for drugs associated with risk of falls

Research studies of interventions include targeted reduction, modification and/or withdrawal of medications. Medications are prevalent in the treatment of morbidity in older adults but multiple medications do increase risk of falling. There is evidence of association between particular drug classes and risk of falling. In an early meta-analysis (where findings from multiple studies are grouped), pooled results of 14 studies indicated that taking type **anti-arrhythmic** drugs (to treat irregular heartbeat) increased the risk of falling (OR 1.22, 95% CI 1.05 to 1.42) (NICE, 2004; Leipzig et al, 1999). **Psychotropic drugs**, that affect the central nervous system, also increased the risk of falls, with pooled data suggesting an increased risk of 1.73 (95% CI 1.52 to 1.97) or 73%.

Other more recent systematic reviews, using improved methodology, have since been published since the NICE clinical practice statement. One review found that the main group of drugs associated with an increased risk of falling included those affecting the central nervous system, including the psychotropics, benzodiazepines, antidepressants and antipsychotics (Hartikainen et al, 2007). There was less evidence for antiepileptic medications and drugs that lower blood pressure – a weak association was found with falling. Some of the drugs used to treat high blood pressure are also used to treat prostate problems in males (called alpha-blockers). Side effects of alpha-blockers include drowsiness and postural hypotension.

Another systematic review found a significant association between the use of **sedatives/hypnotics, antidepressants** and **benziodiazepines** and falls in older people (Woolcott et al, 2009). A list of specific sedatives and antidepressant drugs is given in Table 2. For the purposes of PreFIT, we have broadly categorised drugs into 2 main groups: (1) firstly the **psychotropics,** which predominantly affect the central nervous system (e.g. antidepressants, psychotropic mediations, antimanic and sedatives). We ask that these drugs be targeted for consideration of risk/benefit judgements within medication reviews. Secondly, we ask those conducting

medication screening to consider other potential 'culprit' drugs. These include a broad range, but include cardiac drugs (anti-hypertensive drugs; anti-arrhythmic drugs; vasodilators; diuretics; vestibular suppressants, often used for nausea/sickness; analgesic/painkillers; anticonvulsants and anti-Parkinsonian drugs). Table 3 presents examples of culprit drugs).

8.4 Recommendations for medicines management

The National Service Framework for Older People published guidance on the use of medicines for and by older people (DH, 2001). The purpose of this guidance was to: (a) ensure that older people gained the maximum benefit from their medication to maintain or increase quality and duration of life; and (b) to prevent unnecessary suffering from illness caused by excessive, inappropriate or inadequate consumption of medicine. The NSF set a review milestone that *"all people over the age of 75 should normally have their medicines review at least annually and those taking 4 or more medications should have a review 6-monthly."* (DH, 2001).

8.5 Recommendations for medication reviews in primary care

In 2002, the Department of Health brought medication review to the primary care agenda with recommendations published by the Task Force on Medicines Partnership and National Collaborative Medicines Management Services Programme (DH, 2002). This policy initiative highlighted the importance of medicines management with practical guidance for healthcare practitioners to develop effective review processes, in collaboration with patients. Medication review was defined as: 'a structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste' (DH, 2002). Different 'levels' of medication review were described within this policy document (from Level 0 to Level 3), relating to intensity of review e.g. by level of assessor and whether or not in the presence of the patient.

Table 2 – Psychotropic Drugs that may increase risk of falling

Also refer to Appendix 12 for full list of psychotropic-type drugs with proprietary names (brand names or trade names).

BNF Section 4.1 Hypnotics and Anxiolytics (Night sedation)			
Chloral Betaine	Loprazolam	Oxazepam	Zopiclone
Chloral Hydrate	Lorazepam	Temazepam	
Chlordiazepoxide	Lormetazepam	Zaleplon	
Diazepam	Nitrazepam	Zolpidem	
BNF Section 4.2 Antipsychotic Drugs (Pyschotropic sedation)			
Amisulpride	Haloperidol	Promazine	
Chlorpromazine	Lithium (mania)	Quetiapine	
Flupentixol	Olanzipine	Risperidone	
BNF Section 4.3 Antidepressant Drugs			
Amitriptyline	Lofepramine	Sertraline	
Citalopram	Mirtazapine	Trazadone	
Dothiepin or Dusulepin	Paroxetine	Venlafaxine	
Fluoxetine			

Table 3 - Other 'Culprit' Drugs that may increase risk of falling (Appendix 12)

Also check other 'culprit' drugs from these classes:	
BNF Section 2	**Cardiovascular drugs**
2.2	**Diuretics**
2.3	**Anti-arrhythmic drugs**
2.4	**Beta-adrenoceptor blocking drugs**
2.5	**Hypertension and heart failure**
2.6	**Nitrates, calcium-channel blockers & others**
BNF Section 4.9	**Drugs used in Parkinsonism & related disorders**
BNF Section 7	**Drugs for genito-urinary disorders**
7.4.1	**Urinary retention (alpha-blockers)**

8.6 Drugs that decrease the risk of fracture

For the purposes of PreFIT, we also ask staff conducting medication reviews to consider whether trial participants are taking any drugs that may decrease the risk of fracture. These drugs affect bone growth and are commonly prescribed to women to prevent or treat osteoporosis. Recent NICE guidance specified the use of bisphosphonate drugs as a treatment option for the primary prevention of osteoporotic fractures in susceptible postmenopausal women, also as treatment for postmenopausal women who have already had an osteoporotic fracture. Given that fracture is the primary outcome of PreFIT, we will record number of trial participants prescribed bisphosphonates during the trial period. The names of the bisphosphonate drugs are listed below and are also provided in the Appendix 12 as a laminate.

Table 4 - Drugs that decrease the risk of fracture (Bisphosphonates)

Generic Name	Generic Name
Alendronate Alendronic acid	Risedronate Risedronate Sodium
Etidronate Disodium Etidronate	Sodium Clodronate
Disodium Pamidronate	Strontium Ranelate
Ibandronic acid	Teriparatide
Raloxifene Raloxifene hydrochloride	

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Table 5 - Levels of medication review (DH, 2002)

Level	Description	Comments
Level 0	Unstructured, opportunistic review.	Not to be undertaken
Level 1	Prescription review	Not to be undertaken
Level 2	Treatment review	Not to be undertaken
Level 3	**Clinical Medication Review**	What: A **face-to-face review** of medicines and conditions conducted **with** the patient and their medical notes. Where appropriate, should include the carer. Who by: The GP, hospital doctor, practice nurse, practice support pharmacist specialist nurse, clinical pharmacist or community pharmacy working on a sessional basis. Must always involve the patient. Intervention: Evaluate the therapeutic efficacy of each drug, identify and address unmet therapeutic need, monitor condition progress, discuss aspects of medication with patient.

8.7 PreFIT requirements: medication reviews

For the purposes of PreFIT medication reviews, we have a 2-stage protocol. We ask that **every** trial participant has an initial medication screen. This involves a face-to-face consultation and a **medication screen** by the trained person conducting the falls assessment e.g. practice nurse or health professional from the falls team.

Stage 1 – Medication screen

Please ask the trial participant to bring a listing of their medications to the falls assessment. For those assessments conducted within general practice, it should be possible to obtain a full listing of prescriptions from the practice system. Thus **ALL patients** should have a **medication screen** whereby a visual review is conducted and all prescribed drugs are checked against the list provided in the Appendix 12. We ask you to record on the Falls Risk Assessment Form whether the participant is taking any psychotropic or culprit medications (yes/no). If the general practice or falls team have access to a trained community pharmacist, it is acceptable for the pharmacist to conduct this initial medication screen. We also ask you to screen for any bisphosphonate drugs (yes/no).

Stage 2 – Medication review by GP

For trial participants **currently taking psychotropic or culprit medications**, they should then be referred to their GP or another GP in the practice, for a medication review. This is in line with Level 3 policy guidance, thus:

- All PreFIT participants on psychotropic or culprit medications should have a **comprehensive treatment review** of their medicines. This should be conducted by the GP. The review should be undertaken face to face, wherever possible, with reference to medical notes.
- Any decisions to changed medications must be made by the GP or other medically trained practitioner e.g. hospital consultant, if applicable.
- Recommended factors to discuss with patients during a face-to-face Level 3 Clinical Medication Review are given in the Risk Factor Assessment section (page 65). If required, we can provide more examples of questions to ask during a medication review, based upon those developed by a medication advisory group for AgeUK (DH, 2001)

There are different risk assessment tools to assess medicine-related problems but none have been formally validated. We do not provide you with specific materials for medication reviews but if you would like copies of the DH (2002) Task Force material, please contact Julie Bruce from the PreFIT study team julie.bruce@warwick.ac.uk. We can provide you with links and/or template materials published by DoH e.g. template Patient Information Sheets, Patient Invitation Letters (for prescription reviews), community-based prescription review data collection charts etc.

RISK FACTOR ASSESSMENT d) Medication Review

Screening questions for medication review during the falls interview:

Q1. Are you taking any medications to help you sleep?

Q2 Are you taking any medications to help lift your mood?

Assess all prescribed and over the counter drugs and refer patient to GP for a full medication review if taking any medication for sleep or mood. Also consider other psychotropic and culprit medications – refer to drug list laminate at the back of the manual.

Stage 1 - Medication Screen

Non-medically trained staff

- Ask participant to bring a list of their current medications to the falls assessment.
- Ask if they take any over the counter preparations.
- Conduct a screen of all prescribed medications, ideally in the presence of their medical notes (not always possible).
- Screen their drugs to identify whether on any psychotropic or culprit medications that may be associated with risk of falling. Use the drug listing provided in the Appendix 12 (laminated sheets).
- If taking any psychotropic or culprit medications, explain to the participant that you would like them to have a full medication review by either their own GP or another GP at the surgery.
- If possible, prepare any documentation for the GP e.g. medications, dosages, timing of administration.
- Consider other risk factors and provide a copy of the falls assessment form to the GP or doctor, highlighting risk factors e.g. postural hypotension.
- Liaise with PreFIT team regarding arrangements for medication review appointments. The process will vary across different general practices.
- Refer to Treatment options/ Actions Required box (page 68) for advice about good sleep hygiene and ordering prescriptions from one pharmacy etc.

Stage 2 – Medication review by medically trained staff e.g. GP

- Conduct a full review of all medications, with medical notes and in the presence of the trial participant (face-to-face consultation).
- Conduct the medication review, considering the risk factors (if any) highlighted on the Falls Risk Assessment Form.
- Consider and make adjustments to medications, where indicated.
- Document on the falls assessment form whether any changes made (yes/no). The PreFIT team do not need to know specific changes, just whether or not any modifications were made.
- You must sign and date any changes.
- Arrange follow-up appointment with participant to assess progress post-review, as per good clinical practice.

Treatment options / Actions Required

- Optimise non-pharmacological interventions for chronic conditions
- Taper drugs to lower effective dose or discontinue altogether
- Advise patients to monitor signs, symptoms and when to report
- Advise patients to order prescriptions from one pharmacy to facilitate review
- Advise not to add over-the-counter medications without professional review
- Arrange follow-up appointments, if indicated, to assess impact of revision to medication

Other post-review actions to consider

Possible actions arising from a medication review include:-

- Re-examination of current diagnosis(es) and rationalize treatments according to clinical conditions.
- Further investigations or information ~ this may include biochemical investigations or additional monitoring, e.g. creatinine levels, blood levels of individual drugs, such as lithium etc.
- All changes **should only be implemented by the GP or other clinician (e.g. hospital consultant or falls specialist)** responsible for care.
- Consider access to a pharmacist or prescribing nurse for counseling about medications. Note that any non-medically led initial review must be subsequently discussed with the GP.
- Consider further medication review after periods of brief illness or dehydration episodes.
- The patient should be informed of changes to medications and should be provided with a written copy of the new repeat prescription regimen.
- Provision of medicines support items, such as medicines reminder charts or multi-component compliance aids.

CHAPTER 9

Risk Assessment:

Vision

Risk assessment: Vision

9.1 Vision and balance

Vision makes an important contribution to balance. Control of posture, balance and movement involves a coordinated set of sensory processes that continually encodes information from visual, body awareness (proprioception), sensorimotor and cognitive sources (Lord et al, 2002). For example, we can demonstrate the impact that visual information plays in the role of maintaining balance by standing with our eyes closed; postural sway increases by between 20% and 70% (Lord et al, 2010). As we get older, our ability to judge distances, to detect low-contrast hazards and to process moving visual information is reduced. Consequently, older adults take longer to adapt to multiple sensory cues, particularly moving visual information, which can increase the risk of postural instability and falls. Impaired **visual acuity** (sharpness or fine detail of vision), has been identified as a risk factor for falls in some studies of older adults living independently in the community. Other studies have found no association between visual acuity and falls. Impairments in other systems, such as vestibular function, increase the importance of vision for maintaining balance during movement.

9.2 Vision and balance

Conditions affecting vision in the older adult include degenerative changes and loss of ability to accommodate to close objects – the process by which the eye can focus and adjust to different distances from objects. Eye disease in older adults can include cataracts, glaucoma, age-related macular degeneration. Cataracts are most prevalent in older age groups and mostly develop in those aged over 55 years. Depending upon the size and location, a cataract can interfere with vision. Signs and symptoms include: blurred or hazy vision, reduced intensity of colours, increased sensitivity to glare from lights, particularly when driving at night, increased difficulty with nocturnal vision and changes in the eye's refractive error. These changes can be very gradual but as they worsen, visual symptoms tend to increase in severity. Early research studies examining whether having glaucoma or cataracts increased the risk of falls were inconsistent: some studies demonstrated that treatment to correct vision led to a reduction in falls, but other studies found no reduction in falls nor any decrease in risk of fractures. These inconsistent findings in early studies

may relate to variation in methods used to assess vision e.g. visual impairment, visual acuity, depth perception, contrast sensitivity and others. Some studies vary in their accuracy for diagnosing eye disease, for example, self-report of glaucoma.

9.3 Cataract surgery in older women

However, there is now recent, good quality evidence from one RCT that cataract surgery in older women (over 70 years) does improve visual function and reduce recurrent falling (Harwood et al, 2005). This trial found that women having expedited surgery (within one month) compared to the usual waiting list for surgery (approximately 13 months) had significant improvements in activity, anxiety, depression and a 40% reduction in risk of recurrent falls, and a reduction in risk of fracture.

Recommended treatment of cataracts is based on the level of visual impairment they cause. If vision is barely affected, no treatment is required although a regular check-up schedule is recommended. When a cataract has progressed to the stage that it affects quality of life, surgery is recommended (NICE, 2007). Modern cataract surgery results in rapid visual improvement and many of those treated have good distance vision without the need for glasses (Harwood & Conroy, 2009). Given the recent evidence about benefits of cataract surgery in falls prevention, for the purposes of the PreFIT study, we recommend immediate referral to an optician in the first instance, if a cataract is suspected and this is impacting upon daily activities or quality of life.

9.4 Wearing spectacles

Other common visual problems in older adults relate to the wearing of glasses with an outdated prescription. This could indicate that older adults may not be aware of their declining vision or that they do not perceive the benefits of regular vision assessments (Lord et al, 2010). Cost and/or reduced access to eye care may also present a barrier to having regular vision checks although eye checks are now free for adults in the UK aged over 70 years. Various research studies have investigated the effects of wearing single-lens glasses versus multifocal-lens glasses e.g. bifocal lenses. These studies have found that wearing bifocal glasses does impair the ability of older people to negotiate obstacles and can alter normal step pattern e.g. more likely to come into contact with

the edge of a step when stepping up, or stepping up too high. One research study with one year follow-up found that older adults wearing bifocal glasses were twice as likely to fall compared to those who wore single lens glasses (Lord et al, 2002).

The NICE clinical practice guideline (2004) reviewed studies of visual interventions and concluded that there was insufficient evidence that single interventions targeting vision impairment alone prevented falls, but that referral for visual correction within a multifactorial intervention had a significant impact on falls reduction. Additional benefits from visual interventions include improvements in quality of life. Other reviews have highlighted that bifocal glasses can add to the risk of falls because near-vision lenses impair distance vision and affect depth perception, affecting the ability of an older person to detect environmental hazards (Lord et al, 2010). Therefore the wearing of multifocal/bifocal glasses should be restricted in older adults prone to falls.

9.5 PreFIT requirements: Assessment of vision

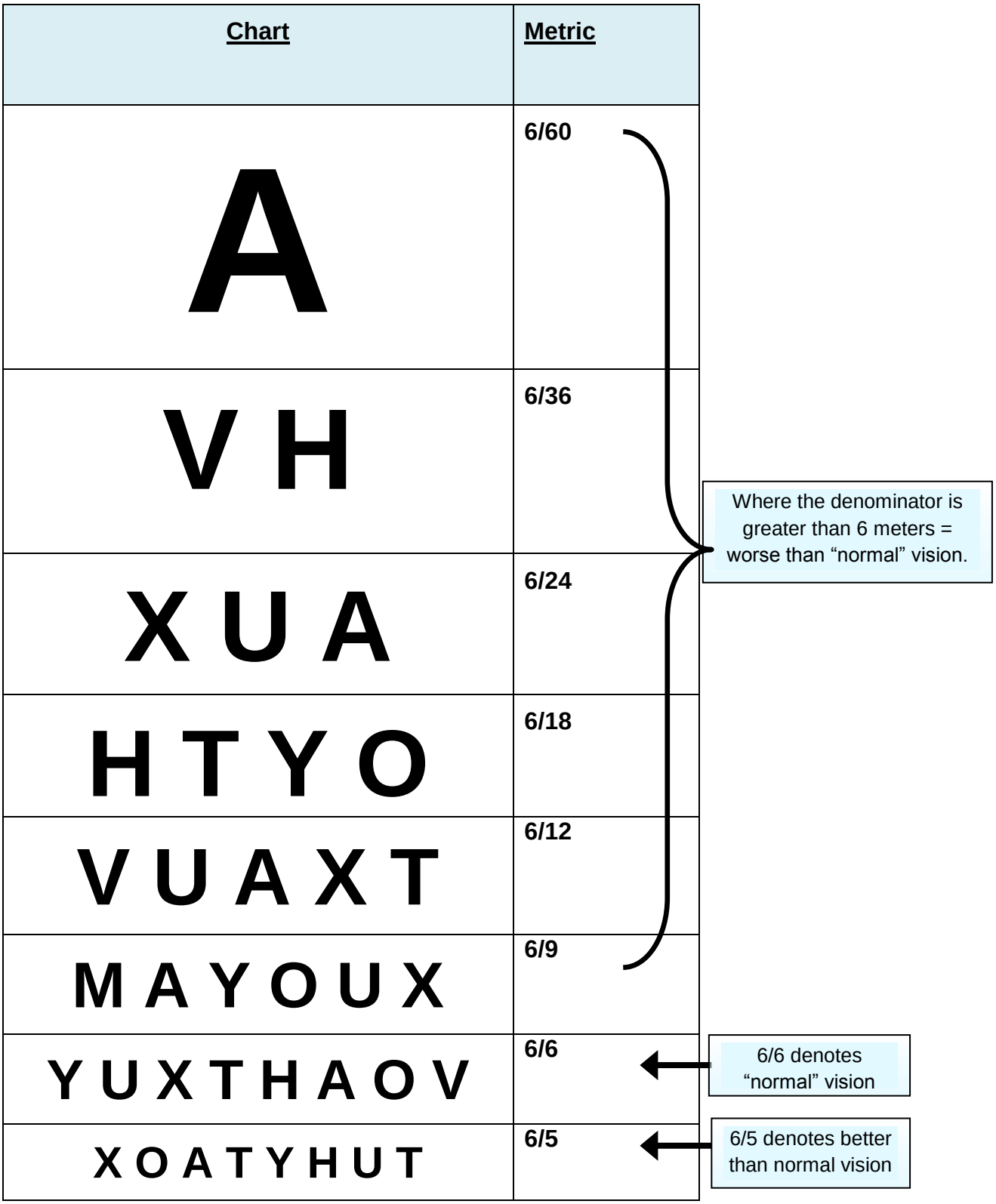
For the purposes of the PreFIT study, we ask healthcare professionals to use simple screening questions and an assessment of visual acuity using the **Snellen chart.** If you have any concerns about glaucoma, cataract or other possible eye disease, referral to an optician for detailed assessment is recommended in the first instance. As this is a primary prevention study, the chances of there being a previously undetected diplopia/double vision problem is relatively low. We ask you to recommend a visit to an optician if the participant wears spectacles but has had no eye test in the last year.

9.6 Snellen Chart

The Snellen Chart is used to test visual acuity. There are different types of chart but the classic type is that with letter of the alphabet – these are coloured black against a white background to provide maximum contrast. Eye charts are configured in different ways, often with different number of lines of letters (e.g. 7 or 11 lines) but with each line being progressively smaller. The Snellen chart should be wall mounted and be at a sufficient distance to approximate ‘infinity’ for the lens to focus – this is taken as 20 feet or 6 metres. From an optical perspective, 6 metres approximates infinity as the difference in optical power required to focus at 6 meters

and infinity is minimal. The person is asked to cover one eye and read the chart from top to bottom, one line at a time.

Figure 2 – Example of a Snellen Chart



9.7 Scoring the Snellen chart

The term 6/6 or 20/20 vision or visual acuity is used to express 'normal' vision or the clarity of vision that most can read at a distance of 6 metres (AOA, 2011). It is expressed as a fraction, with the numerator or upper value referring to the distance in feet between the person and the chart. The denominator (6/***x***) refers to the size of the letters (this actually relates to visual angle) for which the lowest line that is read by an eye with no refractive error. The term is equivalent to 6/6 vision to reflect metric rather than imperial distance (20/20). It denotes that someone can clearly view or focus at 6 metres what should normally be viewed at that distance.

Where the denominator (lower value) is **greater than 6,** this indicates poorer vision than normal. Where the denominator is lower than 6, this indicates better vision than normal. For example, someone with 6/12 vision means that the person can see at 6 metres what a normal person sees at 12 metres, thus their vision is half as good as normal – or objects must be at half the normal distance for them to see them (AOA, 2011). However, a person with 6/5 vision can see objects at 5 metres that a person with normal vision can only see at 6 metres, thus has better than normal vision.

Visual acuity of 6/6 does not mean perfect vision; there are other aspects to vision, including peripheral awareness (side vision), eye coordination, depth perception, colour vision and ability to focus. The fraction of 6/6 does not correlate directly with prescriptions for spectacles because it does not specify the *nature* of the lens problem, only the overall resulting performance. For the purpose of PreFIT, the Snellen chart should be used as **a screening tool** to indicate whether or not the participant should be told to make an appointment to an optician.

RISK FACTOR ASSESSMENT e) Vision

Screening questions for vision

Q1. Have you had your eyes checked by an optician in the last 12 months?

*If yes, continue to Q2. If no, conduct **Snellen Test***

Q2. Has your eyesight changed or have you had any problems with your vision since your last appointment with the optician?

If no, end of visual assessment. Recommend annual eye checks with optician.

*If yes, conduct **Snellen Test***

Examples of exploratory questions about vision include:-

- Any problems with reading? (suggests problem with near vision)
- Any problems with watching TV? (suggests problem with distance vision)
- Do you wear bifocal glasses? Refer to treatment /actions required.

We ask you to recommend a visit to an optician if the participant wears spectacles but has had no eye test in the last year.

Snellen Chart Test

Position of chart

- The Snellen chart should be wall mounted and in a well-light position.
- The person should stand EXACTLY **6 metres** from the chart.
- The distance should be accurately calculated - use the tape measure provided in the manual pack.
- Use the tape provided to mark the floor at the correct distance.
- If the person is wearing reading glasses, these should be removed. If they wear glasses for driving or watching TV (distance vision), these **should be worn** during the test.
- The person can be seated or standing.

Procedure for Snellen Chart Test

- Start with both eyes open. Cover one eye with the palm of the hand or with a sheet of paper. Start with the right eye.
- Ask them to read down the chart until they reach the smallest line of letters they can distinguish on the chart.
- If they cannot complete this whilst covering the eye, an eye patch can be applied.
- Establish the line on the chart where the person can **read half or more** of the letters correctly.
- Repeat the test on both eyes

Scoring

- Record the line at which they can read half or more of the letters correctly whilst wearing distance vision spectacles e.g. 6/12 etc.
- Anything less than 6/6 requires referral to optician for eye check.

Treatment options / Actions Required

- All persons aged over 70 are allowed one free eye test per year. Encourage all participants to attend annual eye check.
- If 6/6 vision or better, no further treatment required.
- If no eye test in the last 12 months and <6/6 vision (with or without spectacles) ask participant to make appointment with optician for eye test.
- If had eye test in the last 12 months but vision has deteriorated since, ask to make appointment with optician.
- If you suspect eye disease or cataracts, either refer to an optician in the first instance for a detailed eye check. The optician can then ask GP to refer to ophthalmology services if required.
- The wearing of multifocals / bifocals whilst walking outdoors **should be avoided** by older people. Advice to wear single focal glasses when walking outdoors or if active indoors (walking, using stairs etc).
- Advice to take care whilst wearing new glasses.
- If visual impairment, consider findings from the home environment assessment and consider referral to occupational therapy.

CHAPTER 10

Risk Assessment:

Foot problems

Risk assessment: Foot problems

10.1 Foot care, footwear and risk of falls

Core podiatry is defined as “the assessment, diagnosis and treatment of common and more complex lower limb pathologies associated with the toenails, soft tissues and the musculoskeletal system with the purpose of sustaining or improving foot health” (Farndon et al, 2009). Up to 1 in 3 older people suffer from foot problems, such as foot pain, toe deformity, weakness or restricted range of motion (Spink et al, 2011; Menz et al, 2010). These problems are common reasons for attending primary care services. Other UK foot surveys suggest that the main foot conditions affecting older people requiring core podiatry include nail problems, corns, calluses and toe deformities (Farndon et al, 2009).

Foot problems are risk factors for falling: studies of older people with a history of multiple falls suggest that they are more likely to have foot impairment, such as pain or deformity (Spink et al, 2011). Other studies have found that poor footwear or the presence of a corn or bunion were significant independent risk factors for falls (Dolinis et al, 1997). Evidence regarding inappropriate footwear and falls comes from both research studies in the laboratory setting but also from population (epidemiological) studies investigating risk of falls in older adults. Shoes with an elevated heel of even medium height (4.5cm) have been found to significantly increase postural sway and impair overall balance performance (Menant et al, 2008b). Other features of ‘inappropriate’ footwear include shoes without laces, straps or buckles, reduced sole contact area, soft-soled shoes and those without heel support (Menant et al, 2008b; Spink et al, 2011). A review of the contribution of footwear to risk of falls concluded that walking barefoot or in socks increased the risk of falls indoors, although most evidence comes from studies of older adults resident in care homes (Menant et al, 2008a). Shoes with a higher heel cuff or collar (refer to Figure 3) provide mechanical ankle support and can help prevent inversion.

10.2 National guidance for foot care / footwear in older adults

The efficacy of including foot/footwear/podiatry assessments within multifactorial falls programmes was reviewed by NICE and within systematic reviews of falls prevention

(Gillespie et al, 2003; Gillespie et al, 2009; Gates et al, 2008; NICE, 2004). These reviews found there was no overall, conclusive evidence of benefit of a stand-alone a foot assessment and treatment intervention in preventing falls. Although the NICE Clinical Practice Statement and AGS/BGS policies agree that examination of the feet and simple advice about footwear should be included within any MFFP programme, these guidelines did not specify which assessment or intervention activities should be undertaken (NICE, 2004).

One trial published since the policy guidance found that a multifaceted podiatry intervention significantly reduced the rate of falls in community dwelling older adults with disabling foot pain compared to routine podiatry care (Spink et al, 2011). The intervention comprised a foot and ankle exercise programme, a prefabricated supportive orthoses (moulded foam insert), advice on footwear, subsidised footwear and general falls education advice booklet. Rate of falls and fractures were lower in the intervention group and strength, balance, range of motion were also significantly improved compared to those receiving usual podiatry care (Spink et al, 2011). Authors concluded that these components were inexpensive and relatively easy to implement, suggesting they could be incorporated into routine podiatry care.

10.3 PreFIT Study: assessment of feet and footwear

For the purpose of PreFIT we ask that you conduct a visual examination of feet to check for obvious bunions, hammertoes, calluses or nails that may cause pain or gait disturbances. If you are concerned about numbness or foot positioning, you should conduct a simple check of propriception. Access to NHS community podiatry services does vary from region to region; some NHS services provide free podiatry or chiropody to diabetic patients.

i. Procedure for conducting tests of proprioception and numbness

Test for proprioception

- The person should be seated on a chair with their shoes and socks removed.
- Explain the procedure – you are going to move their big toe in different directions and want them to specify whether the toe is being moved up/down (or backwards/forwards). This will be repeated on both feet.
- Ask them to close their eyes.
- Hold the right foot and grasp the toe at the sides with your fingers.
- Move the big toe by 2mm in different directions and ask the person to report the direction of movement (either up, down, backwards or forwards).
- You can do this up to 3 times on the toe (if person cannot follow first attempt)
- Incorrect responses may indicate neurological illness.

Test for numbness/Sensation check (conduct if you suspect foot numbness)

- Person can be seated or lying, but with socks and shoes removed
- Explain procedure – you will need a cotton wool ball
- Rub the cotton wool ball lightly across the sternum as a reference guide (ask if they can feel the sensation)
- Ask them to close their eyes
- Start with the R foot, lightly brush cotton wool across the toes
- Ask if they can feel the sensation. Ask whether feels the same or different to the sensation on the sternum.
- Repeat on L foot. Ask whether any difference between L or R foot.

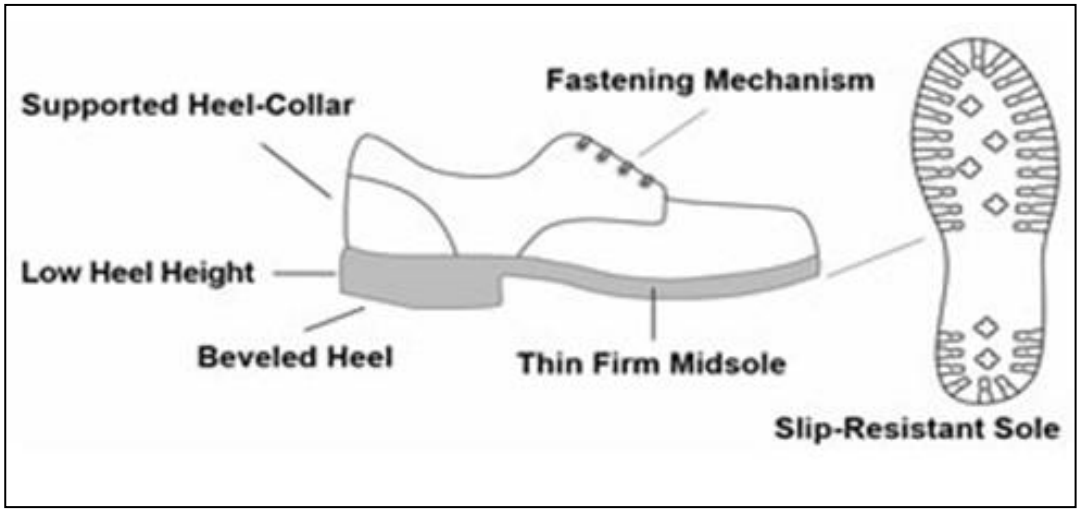
10.4 PreFIT requirement: provide advice about feet and footwear

Assessment of footwear will be largely based upon what the study participant is wearing at the time of interview, however we ask that you assess footwear and provide simple advice about what is appropriate footwear. Footwear can cause foot problems therefore by helping patients to recognise and make sensible choices about footwear can help prevent the development of new problems or any deterioration of existing foot conditions. Simple footwear advice includes: wearing cotton socks and leather shoes; ensuring that the shoe is properly fitted and wide enough to prevent pressure on the toes; and that the shoe has features

demonstrated in Figure 3. Preferably, shoes should be worn both indoors and outdoors but if slippers are worn indoors, they should adhere to the same criteria - thus have good heel support, have a non-slip sole and not be worn or frayed.

Advice about care of the feet is also provided within the AgeUK leaflet which is provided to all study participants referred for MFFP. If a participant also requires onward referral to exercise therapy, assessment foot positioning, gait and balance will be undertaken within the Otago Exercise Programme.

Figure 3 - Recommended shoe features for older people



Features of shoes recommended for older people:

- Shoe has a supportive heel-collar or ‘closed cup’;
- Low heel height of less than 1.5” height (2cm);
- Heel is slightly beveled;
- Shoe is fastened using laces, straps or buckles for support;
- A thin firm midsole to allow sensory input;
- Slip resistant sole
- A wide fitting to allow toe movement.

RISK FACTOR ASSESSMENT f) Foot Care and Footwear

Screening questions for foot care

Q1. Do you have any problems with your feet?

Q2. Any pain in your feet?

Q3. Any numbness in your feet?

Q4. Do you have diabetes?

Q5. Do you attend chiropody/podiatry services?

Assessment

- Ask to remove shoes and socks. Check for marks on the skin after removal of socks and shoes.
- Conduct visual inspection – look for bunions, corns, calluses, hammertoes, in-growing or overgrown toenails.
- Check for foot ulcers and assess whether any foot numbness.
- Only if you suspect numbness, then conduct the simple proprioception test.
- Check type and condition of footwear.
- Consider gait from the TUGT screening test and whether gait indicative of underlying disease e.g. Parkinson's, stroke or hip/knee osteoarthritis.

Recommended advice

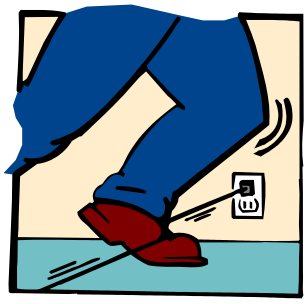
- Wear cotton socks and leather shoes that 'breathe'.
- Check shoes for stones before wearing.
- Tip of shoe should extend 1" beyond great toe and should be wide enough for metatarsal heads without pressure areas – refer to Figure 3.
- Wear shoes with good arch support, closed heel and heel height less than 1.5" (3.8cm).
- Wear shoes with soles that are at least as wide as the sole of the foot, with non-slippery surface.
- Wear shoes that are not too thick as to decrease sensory input or create a hazard for tripping.

- Preferably, shoes should be worn both indoors and outdoors but if slippers are worn indoors, they should adhere to the above criteria - thus have heel support and not be worn or frayed.

Treatment options / Actions Required

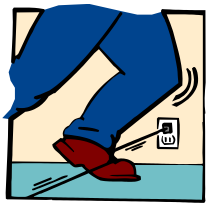
- Refer to local podiatry/chiropody services if available.
- Consider referral to physiotherapy services for balance retraining if you are concerned about gait style or foot placement.
- Provide advice as above and give AgeUK leaflet which contains foot care advice.
- Consider referral to relevant secondary care services if indicated e.g. diabetic services.

CHAPTER 11



Risk Assessment:

Home Environment



Risk assessment: the home environment

11.1 Environmental hazards

Environmental hazards in the home are often cited by policy makers and older people as significant risk factors for falls in older adults living in the community. However, it is difficult to single out the most effective intervention within any home environment assessment/modification programme. The 2004 NICE guidance reports on different studies of home hazard modification and safety interventions. There is one good quality trial demonstrating that home hazard assessment with a supervised modification programme is effective in reducing falls in those discharged from hospital. However, the association with domestic hazards and falling has been generally controversial – in those without a history of falls in the previous year, there is no evidence of effectiveness (NICE, 2004). Of the trials of home hazard modification in previous fallers (secondary prevention), six trials have reported effectiveness, although this observed effect was thought to be unlikely to be from the home hazard interventions alone, because of the reductions in falls which occurred outside of the home (Gates et al, 2008; NICE, 2004). The evidence suggests that home hazard removal and advice about functional activities is most effective in reducing falls in individuals with visual impairment (Gates et al, 2008).

Despite the controversy, what *is* important is that benefit is only achieved if home hazard assessment is carried out through a functional assessment and is followed-up with specific intervention – although this applies to all components of multifactorial assessment and intervention programmes, not just home hazard assessments. There is no evidence to support merely screening for home hazards without direct observation of the individual carrying out functional tasks within their home environment (Clemson et al, 2008; Pighills et al, 2011). Equally, the evidence suggests that to enhance adherence, older people have to acknowledge that the identified hazard is a potential falls risk and own the solution through a joint problem solving process (Clemson et al, 1999).

11.2 National guidance

The guidance from NICE acknowledges that a suitably trained member of the health care team can conduct home hazard assessments - this may include a clinician,

occupational therapist, nurse, physiotherapist, social work, or other trained assessor. The AGS/BGS guidance also states that environmental assessment of home safety should be conducted and that interventions should include the adaptation or modification of the home environment. The purpose of is to mitigate identified hazards in the home, evaluate and intervene to promote the safe performance of daily activities.

11.3 PreFIT requirements: assessment and treatment

For the purposes of PreFIT, it is not a prerequisite that a home assessment is conducted for every participant. However, if you have concerns about the safety of performing activities at home, either from the detailed falls history or the presence of potentially hazardous features, we do ask that you refer to relevant services for a home assessment, for example, occupational therapist or social services. An example would include someone with a history of repeated stumbles during a particular activity e.g. rising from the bed or toilet, (or climbing stairs) or place where there may be obstacles on the floor.

In addition to onward referral of selected participants, we ask that you provide ALL participants with the AgeUK advice leaflet (Appendix 1) and a PreFIT study Tip Sheet “Staying Safe at Home” (Appendix 7). These leaflets provide simple checklists for checking the home environment.

RISK FACTOR ASSESSMENT g) Environmental Hazards

Screening questions for environmental hazards

Q1. Do you use the furniture to support you when walking around the house?

Q2. Do you have difficulty getting out of a chair or rising up from the toilet?

Q3. Do you have stairs at home or steps up to your front door?

Q4. How do you cope with going up and down stairs?

Q5. Do you use a walking aid?

Assessment

- Consider responses from falls history interview e.g. whether the participant reported tripping indoors or outdoors. Consider responses to screening questions about stairs.

Recommended advice

- Advise to check for any hazards at home e.g. remove anything that will impede or obstruct their path; uneven walking surfaces, such as cords, area rugs, clutter, or furniture etc.
- Install aid to raise the toilet seat, if needed.
- Check on outdoor walking paths, ensure these are well-lit both day and night.
- Install blinds or curtains that easily accessed and adjusted to avoid glare – and let in light if darkened room.
- Advise to move commonly used objects so they are within reach.
- Avoid reaching overhead or bending over and lifting from floor.
- Consider installation of handrails to stairs or hallway if necessary.
- Advice not to obstruct view of feet and not to carry bulky or heavy items up or down stairs
- Suggest asking for help when changing ceiling bulbs, curtains, smoke detector batteries etc.
- Advise to put on lights when rising to the bathroom in the middle of the night.
- Advise to use heating in winter months, particularly for those living alone.

Treatment options / Actions Required

- Consider referral to occupational therapy services, if available, for assessment of home environment.
- Give AgeUK leaflet which also contains home safety advice.
- Give PreFIT Home Safety Tip Sheet which contains home safety advice

CASE STUDY 1

General practices have agreed to participate in the PreFIT study and have been randomised to deliver MFFP. Staff at these practices have been trained by the PreFIT study team in falls assessment.

Assessment

A 73 year old lady is a trial participant. She returns her screening survey form and is considered at risk of falling although has not previously attended any falls service. She is invited for MFFP assessment; she is initially reviewed by the practice nurse and then the GP. She is worried that she is a bit unsteady and has had a few near misses but no actual falls. There is no postural drop in her BP, her sole medication is a low dose non-steroidal anti-inflammatory (NSAID) for shoulder pain, but is otherwise healthy – although her shoulder only limits her slightly, she still walks her dog ½ mile every day.

Her vision is normal and she had an eye test 9 months ago. Her feet show no major issues with normal proprioception. On the TUGT test, she does complete it within 14 seconds but has a bit of sway. She lives independently with no services and doesn't use a stick or walking aid.

Intervention

- Referral to physiotherapy for gait and balance retraining (Otago Exercise Programme).

This example shows somebody who is starting to develop a risk for falls but has no major problems. We don't know if early intervention helps here but the PreFIT study will help answer this type of "primary" prevention issue.

CASE STUDY 2

Assessment

An 82 year old man is a trial participant. The gentleman has had 3 falls in the last year, two when walking along a pavement, stepping on or off kerbs, and one coming down a short flight of stairs. He has not attended any services for these falls. He has hypertension and prostatism (gets up to pass urine twice during the night). He lives with his wife and she has early dementia. He does the shopping and cooking, and he can walk around the shops unaided.

Drugs: on bendroflumethiazide (BP), amlodipine (BP) & doxazosin (alpha blocker for prostate and BP) plus aspirin. He has started using temazepam more frequently to help him sleep at night. On examination, he wears glasses (bifocals) and has recently changed from separate reading and distance glasses although there was no deterioration in his vision when the optician checked a few months ago apart from noting a very early cataract. His BP is lying 155/87 & standing 134/84 (asymptomatic). His feet are in good shape. His TUGT was 18 seconds (so mildly increased) and he was also rather unsteady on turning.

Intervention

- Referral to physiotherapy services for gait and balance retraining.
- He is also given advice to go back to the optician for separate glasses (?cause of fall on steps).
- His medication review leads to a change in his alpha blocker to an alternative drug for his prostate that doesn't cause postural hypotension.
- His poor sleep is due to worries about his wife's dementia therefore his GP organises a separate review to look at how he might be better supported in this role, including linking in with a local carers' support group. His use of temazepam is discussed and the patient and GP agree to try weaning it and then not taking it for 6 months.
- Home hazard assessment to address safety on the stairs, night lighting etc

Thus ‘treatment’ is: (a) physiotherapy; (b) optician; (c) medication modification with review within 3 to 6 months; (d) home environmental assessment; and (e) advice and support (social).

This example shows a patient who is starting to fall but who has some clearly modifiable risk factors that can be managed in primary care, alongside simple factors such as changing spectacles. Minimising sedatives can reduce falls by 30%. Relatively straightforward medication reviews can sometimes solve postural hypotension. This is the sort of patient that the Pre-Fit study might show as benefiting from physiotherapy and from a GP-led medication review.

CASE STUDY 3

Assessment

A 77 year woman consents to Pre-Fit. She has had multiple unwitnessed falls, including one with a long lie on the floor - the patient has a number of bruises including on the face. She never remembers actually falling. The patient has treated angina, but still gets chest pain on hills and gets palpitations once a fortnight or so. Her TUGT is normal. BP lying is 175/90 and standing 120/68 (postural hypotension). Her heart rate is 51/minute (bradycardia). Her eyesight is normal on the Snellen chart whilst wearing distance spectacles and her feet are in good condition. She lives alone, gets to the shops by taxi and is otherwise independent.

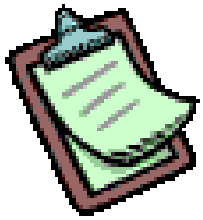
Drugs: She is on multiple medications including perindopril, isosorbide mononitrate, bendroflumethiazide, doaxazosin and amlodipine plus atenolol.

This patient has **red flags** for syncope - multiple unwitnessed falls without recollection of falling plus facial bruises. She has difficult postural hypotension as may still need to take cardiac medication to prevent angina. The medication review could again be done in primary care but with possible syncope and palpitations, this patient would probably benefit from a comprehensive falls/syncope service assessment. Falls here may be multi-factorial. Exercise in a patient with symptomatic angina may need careful individual planning.

Intervention

This patient is eligible for referral to a consultant-led falls service, either to local community falls service (as long as consultant-led) or secondary care referral.

CHAPTER 12



MFFP Assessment (who, where and when)

12. PROCESS FOR REFERRAL AND ASSESSMENT

12.1 Process for referral for MFFP assessment

General Practice staff are responsible for conducting the balance survey to identify trial participants with a history of falling and/or poor balance. This procedure is described within the practice manual. These balance forms are then coded by the PreFIT office and referral forms are generated. Based upon responses to the balance survey, trial participants considered at high or intermediate risk of falling are eligible for MFFP assessment. These include multiple fallers (high risk), single fallers and those with balance problems (intermediate risk).

As the trial is pragmatic and delivered within 'usual' clinical care, there are different models for referral and assessment. The 2 most common models for assessment are: (a) MFFP assessment by practice nurses or other trained staff within the general practice; (b) MFFP assessment by falls service team.

The PreFIT office will generate the referral forms; these forms give name, contact details and PreFIT ID number for each participant that requires a falls assessment. These forms also clearly state that the trial participant requires MFFP assessment as per the PreFIT intervention manual. The practice or falls service must then arrange a suitable time and venue for initial assessment.

a) MFFP Assessment by General Practice Staff

Where the general practice has responsibility for conducting falls assessment, they should arrange an appointment for each trial participant. Based upon feedback from practices taking part in the pilot phase of the study, we found that the optimal model was where practice staff established set up dedicated falls clinics e.g. morning or afternoon clinic to assess trial participants. The PreFIT team will liaise with individual practices to discuss processes for monitoring each participant.

b) MFFP Assessment by Falls Service Team

The falls service should arrange a suitable time and venue for assessment. Some falls services inform patients by telephone with a follow-up confirmation letter of

time/date of appointment. The PreFIT team will liaise with the falls team to discuss optimal processes. We can provide template documentation if necessary e.g. invitation letters. In the Appendix 9, there is a document providing advice for making the first telephone call to study participants.

12.2 Who conducts the MFFP assessment?

The MFFP assessment must only be conducted by staff (from general practice or local falls service) that have completed training in the PreFIT intervention. Therefore all personnel likely to be involved in delivery of the trial intervention must attend training sessions provided by the PreFIT study team. The local research nurse will liaise with staff to arrange training. We also provide short training to general practitioners responsible for conducting medication reviews.

12.3 Where should the MFFP assessment be conducted?

The MFFP assessment can be conducted at the general practice, or any other suitable location. Assessments can be undertaken in the 'usual' location for comprehensive falls assessment (e.g. community clinic or falls clinic located within secondary care). Ideally, the location of assessment should be conducted near to the general practice to facilitate the medication reviews. For some areas, falls assessments have been conducted by the falls team within the general practice. As this is a pragmatic clinical trial, procedures will vary from region to region.

12.4 How long is the MFFP assessment?

The MFFP assessment can be conducted as soon as staff complete PreFIT MFFP training and when trial participants have been identified e.g. balance screening survey completed and referral forms generated. We ask that the assessments be completed within a timely manner (e.g. ideally within 6-8 weeks of receipt of referrals). As described above, the general practice or local falls service should make an appointment for each trial participant. We recommend that the appointment should be for **45 to 50 minutes.** This is based upon previous falls assessment literature whereby the average falls assessment lasted between 30 and 45 minutes.

For patients who have fallen multiple times, this appointment may take up to 50 minutes e.g. to explore causes and consequences of recent falls.
Assessment appointments can be booked as joint appointments. For example, the trained practice nurse may assess some risk factors e.g. conduct the falls history interview, conduct the Timed Up and Go test, consider gait and balance during the test, take lying and standing BP, assess condition of feet, conduct the footwear check and ask about home environment and circumstances. The practice nurse (or other health care staff) will also be trained in how to screen for psychotropic and culprit medications.

The **GP must** review all initial tests conducted by the practice nurse and should consider red flags for falls and/or poor balance. The GP must also complete the medication review and must review and sign off any recommended treatment pathways that have been identified by the practice nurse. The time for GP assessment may take 10-15 minutes.

12.5 Can we assess other factors during the MFFP assessment?

For all **trial participants**, we ask that you adhere closely to the PreFIT study manual and only assess the risk factors listed within the manual. It is essential that staff responsible for delivery of the trial intervention adhere to the recommended PreFIT assessment and treatment pathways in order to 'standardise' the intervention across different centres. For all other non-trial patients attending falls services, you can conduct assessments in the usual manner according to your local pathways.

12.6 Tracking trial participants

It is important for the PreFIT study team to track throughput of trial participants to avoid overburdening of local services. We aim to work closely with general practices and local falls services to stagger participant throughput wherever possible. The local research nurse or PreFIT office will liaise with practices and services on a regular basis to monitor throughput. We have developed template Microsoft Excel spreadsheets which list anonymised IDs of each trial participant and ask that these be returned to the main office on a monthly basis. If you have any queries, please feel free to contact the PreFIT office at any time.

12.7 Trial Reporting Procedures

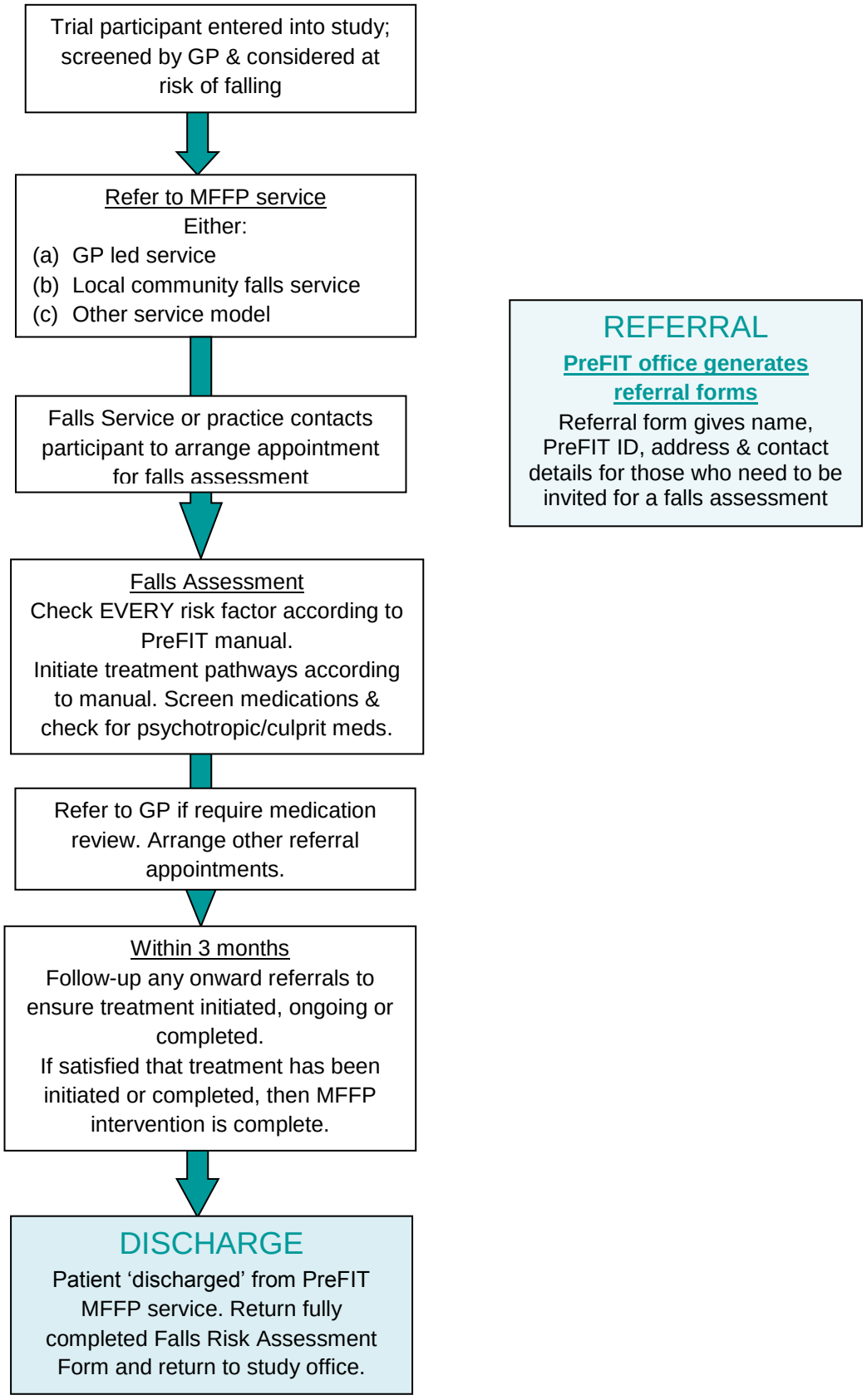
There is one document to be completed for each trial participant – the Falls Risk Assessment Form. Please keep a copy of the form at the practice or with the falls team and return to the original to the PreFIT office (or store in the PreFIT "Red Box file").

Form 1: Falls Risk Assessment Form

The Falls Risk Assessment Form should be completed during the assessment interview with the study participant.

- Each risk factor should be assessed according to the guidance within this manual. This form lists each of the main risk factors and allows you to record details of onward referrals and treatment decisions.
- Different staff members may be involved in the assessment process therefore the form details of who conducted the assessment (e.g. designation) must be provided.
- The medication review section must be signed by the GP who conducted the full medication review.
- Please take a copy of the completed form to be stored in the patient's medical records. Please return the original MFFP form to the PreFIT office (or red box).
- The local PreFIT research nurse of study office may get back in touch to discuss any treatment actions/outcomes relating to onward referral.
- If the participant has been assessed and no treatment or onward referral is required, the assessor should complete the Falls Risk Assessment Form and return to the Red Box File held in the practice).

Figure 4 - Participant pathway for MFFP assessment and treatment



CHAPTER 12. KEY POINTS

- Referral forms are generated by the PreFIT office and given to the falls service or general practice responsible for assessments.

- There is one MFFP document to be completed and returned to the study office: the Falls Risk Assessment Form.

- The Falls Risk Assessment Form is completed during the assessment.

- Screen for EVERY risk factor on EVERY participant. Also screen medications to identify any psychotropic and culprit drugs. If taking psychotropic or culprit drugs, refer to GP for full medication review.

- Record whether and any onward referrals made e.g. referral to physiotherapist or hospital consultant etc.

- Store forms in PreFIT box file until referrals /GP appointments have been made.

- Once all sections of the form have been completed and signed, take a copy for your own service or GP practice and then return the original form to the PreFIT study office.

- The study office will liaise with you regarding monthly monitoring to keep track of trial patients e.g. those assessed / those waiting to be assessed.

CHAPTER 13

Adverse Event Reporting

13. REPORTING ADVERSE EVENTS

13.1 Introduction

This section defines the different types of adverse events and the process for reporting these events to the study team. The accurate and timely reporting of adverse events is a requirement of Good Clinical Practice. The Chief Investigator of the PreFIT study (Professor Sallie Lamb) is responsible for the reporting of relevant adverse events and for the safety reporting of participants for the study Sponsor at regular time intervals. Reports are submitted to the funder, to the Data Monitoring Committee, (who overview trial safety), to NHS Health Technology Assessment panel and to the Ethics Committee.

All staff that have contact with trial participants have a responsibility to note any adverse events mentioned by participants and communicate these to the Chief Investigator via the trial team. This includes **serious adverse events** and **other reportable events**. The incidence of serious events should be monitored during intervention sessions. Time to first fracture will be monitored as the main safety outcome measurement.

Each participant will have had a clinical assessment done – this will provide information on relevant co-morbidities, procedures etc. The PreFIT study population are all aged over 70 years therefore we do not consider the normal ups and downs of chronic diseases of old age to be adverse events – i.e. osteoarthritis etc. It is expected that participants will experience some uncomfortable effects of participation in the intervention – for example muscle or joint soreness in response to exercise, feeling unwell or anxious after withdrawal of medication. These and similar effects are entirely to be anticipated, and provided they are short lived or dealt with through clinical management should not be reported as adverse events.

Events are only to be reported if they occur during the following time periods:

- During contact time with any healthcare professional delivering the intervention;
- During an intervention session (e.g during MFFP assessment);

- If receiving an exercise intervention (e.g. if referred for exercise), an event occurs whilst undertaking study exercises prescribed by the study physiotherapist – either supervised or unsupervised.
-

13.2 Events that DO require reporting

If a study participant is referred for MFFP, healthcare professionals will be required to report serious adverse events that have, in their opinion occurred **directly as a consequence of the treatment** and were **unexpected, unintended or unanticipated**. Thus any event occurring as a direct consequence of the treatment and resulting in death, threat to life, hospitalisation, disability or incapacity should be reported.

Events to be reported should only include those that require professional medical attention, including, but not restricted to:

- Injurious falls resulting in fracture or serious injury
- Myocardial Infarction
- Uncontrolled Angina
- Cerebral vascular accident

Musculoskeletal injuries **requiring professional medical attention** including serious sprains, joint dislocation, falls or other injuries occurring as a direct consequence of the intervention (i.e. whilst participating in the intervention in real-time) should also be reported.

You should complete an **Adverse Event Notification** (Appendix 5) immediately after becoming aware of any suspected adverse event. The Trial Coordinator (Emma Withers) should be informed of all such events as soon as possible, and when serious always **within one working day**. (Box 8).

13.3 Other Reportable Events

Where attribution to the intervention or “expectedness” cannot be confirmed, the event should be reported to the Trial Coordinator (Emma Withers). These incidents will be reviewed by the Chief Investigator. If you are unsure about a particular event, please contact the study team for advice.

13.4 Role and responsibility of healthcare professionals delivering the MFFP intervention

The healthcare professional primarily responsible for delivery of the intervention should complete an Adverse Event Notification Form immediately after they become aware of any reportable adverse event. The Trial Coordinator should be informed of all such events as soon as possible, and **when serious, always within one working day.**

Box 8 - Adverse Event Notification form (refer to Appendix 5).

- Enter the participant's identification number onto the front sheet
- Section 1 – participant details: enter the participants initials and date of birth
- Section 2 – Reason for reporting: indicate in this section if the event is a death, life threatening event, hospitalisation, disability/incapacity or other medically significant event. If it is another medically significant event please include details i.e.(but not restricted to) falls, myocardial infarction, uncontrolled angina, cerebral vascular accident, musculoskeletal injuries requiring medical attention—serious sprains, joint dislocation etc.
- Section 3 – Case Description: enter the date that you deem the event became serious, details of any relevant medical history and details of the event – continue these descriptions on a separate sheet if necessary (please ensure that you include the participants ID number, section number, your signature and the date of completion on the additional sheet)
- Section 4 – Trial Treatment: Indicate if you feel that the event is related to the trial and provide details of why you feel the event is related i.e. took place during an exercise class, indicate if you have discharged the participant from any further trial related procedures as a result of the event i.e. completion of any bending exercises and if the participant has been discharged from intervention activities the date of discharge
- Section 5 – Your details: please complete in block capitals

Then please fax the form to the Warwick Clinical Trials Unit on

024 7615 0549.

13.5 Reporting a Death

If the therapy team are informed about the death of a ***trial participant during the study period please let us know as soon as possible in order to avoid any possible distress to the bereaved family caused by inappropriate follow up.*** Please inform the local research nurse immediately. The local research nurse has copies of the "**Event Notification Form"** (Appendix 6). In the event of a death, the local research nurse will complete this form and fax it **immediately** to the PreFIT study team.

13.6 Withdrawal from study

If a participant would like to withdraw from the study, please inform the local research nurse immediately. The local research nurse will complete the **Event Notification Form** and will fax this to the PreFIT study team.

13.7 Complaints procedure

In the unlikely event that a participant or potential participant makes a complaint about any aspect of the trial, please inform the local research nurse. The local research nurse will complete the **Event Notification Form** and will fax this to the PreFIT study team. It is our experience that complaints are rare from trial participants. If a complaint does occur it can usually be dealt with most effectively if the scientist in charge of the trial contacts the participant as soon as possible to discuss the problem.

13.8 Events that do NOT require reporting

We expect that participants might experience some uncomfortable effects of taking part in the intervention – for example, feeling unwell or anxious after withdrawal of medication. These effects are entirely to be anticipated, and provided they are short lived or dealt with through clinical management should not be reported as adverse events.

If you have any queries or concerns about adverse event reporting, please contact the study team for advice at prefit@warwick.ac.uk.

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List of Appendices